UNITED STATES DISTRICT COURT
SOUTHERN DISTRICT OF NEW YORK

HOU LIU and AMY FU, Individually and on Behalf of All Others Similarly Situated, Lead Plaintiffs, v. INTERCEPT PHARMACEUTICALS INC., MARK PRUZANSKI, SANDIP S. KAPADIA, RICHARD KIM, and RACHEL MCMINN Defendants.	No. 1:17-cv-07371-LAK CLASS ACTION JURY TRIAL DEMANDED

AMENDED CLASS ACTION COMPLAINT

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TABLE OF DEFINED TERMS AND ABBREVIATIONS

Term	Definition
2016 Prospectus Supplement	Intercept's Prospectus Supplement filed with the SEC on July 1, 2016 for its $447.7 million public offering
2016 10-K	Annual report for the year ended December 31, 2016, filed with the SEC on Form 10-K on March 1, 2017
AC Transcript	Transcript of the Gastrointestinal Drugs Advisory Committee Meeting on April 7, 2016
ALP	Alkaline Phosphatase
ALT	Alanine Amino Transferase
AST	Aspartate Aminotransferase
Briefing Package	The FDA's Briefing Package dated April 7, 2016 regarding the new drug application for Ocaliva as a treatment for PBC
CEO	Chief Executive Officer
CFO	Chief Financial Officer
Class	All persons who purchased or otherwise acquired Intercept common stock in the United States or on the NASDAQ Global Select Market from June 9, 2016 through September 20, 2017, both dates inclusive.
Class Period	June 9, 2016 through September 20, 2017, both dates inclusive.
Company	Intercept Pharmaceuticals, Inc.
Dear Healthcare Provider Letter	Intercept's September 12, 2017 letter to healthcare providers warning of the danger of prescribing an excessive dose of Ocaliva to patients with late-stage PBC.
Defendants	Individual Defendants together with Intercept
EMA	European Medicines Agency
Exchange Act	Securities Exchange Act of 1934
FDA	United States Food and Drug Administration
FOIA	Freedom of Information Act, 5 U.S.C. § 552
Intercept	Intercept Pharmaceuticals, Inc.
Interconnect	Intercept's online patient services hub for Ocaliva
Kapadia	Individual Defendant Sandip Kapadia, Intercept's CFO

Term	Definition
Kim	Individual Defendant Richard Kim, Intercept's Senior Vice President of Commercial U.S. during the Class Period
Lead Plaintiffs	Hou Liu and Amy Fu
NASH	Nonalcoholic Steatohepatitis
NDA	New Drug Application
Ocaliva®	Ocaliva a/k/a OCA or obeticholic acid
PBC	Primary Biliary Cholangitis
Potential Side Effects	Increased risk of liver injury and death associated with Ocaliva use
Pruzanski	Individual Defendant Mark Pruzanski, Intercept's CEO
PSUR	Periodic Safety Update Reports
SAE Chart	Chart showing the serious adverse events that were the subject of the FDA's Safety Alert and Safety Announcement
Safety Alert	The FDA's September 21, 2017 Safety Alert warning doctors about reports of death and serious liver injury linked to Ocaliva
Safety Announcement	The FDA's September 21, 2017 Safety Announcement explaining reports of death and serious liver injury linked to Ocaliva
SEC	United States Securities and Exchange Commission
Urso (a/k/a UCDA)	Ursodiol, the standard of care to treat PBC before Ocaliva was approved

GLOSSARY

Term	Definition
Accelerated Approval	Special expedited FDA approval process for products being tested to treat serious diseases or fulfill an unmet medical need.
Advisory Committee	Advisory committees provide the FDA with independent advice from outside experts, industry representatives, and patient advocates on issues related to drug products and approval.
Alanine Amino Transferase ("ALT)	Enzyme leaked from injured liver cells that, when elevated, indicates liver damage.
Alkaline Phosphatase ("ALP")	Enzyme leaked from injured liver cells that, when elevated, indicates liver damage.
Aspartate Aminotransferase ("AST)	Enzyme leaked from injured liver cells that, when elevated, indicates liver damage.
Cirrhosis	A chronic disease of the liver marked by degeneration of cells, inflammation, and fibrous thickening of tissue.
Child-Pugh Score	A diagnostic tool used to assess the prognosis of chronic liver disease. Child-Pugh Score A is early stage liver damage, whereas Child-Pugh Score B is moderate liver damage, and Child Pugh Score C is late-stage liver damage.
Bilirubin	A compound processed by the liver that, when elevated, indicates liver damage.
CONTROL Trial	Phase II clinical trial of Ocaliva for the treatment of NASH.
Food and Drug Administration ("FDA")	A federal agency of the United States Department of Health and Human Services responsible for, *inter alia*, protecting and promoting public health through the control and supervision of prescription drugs.
European Medicines Agency ("EMA")	A decentralised agency of the European Union (EU) responsible for the scientific evaluation, supervision and safety monitoring of medicines in the EU. The FDA's European counterpart.
Hepatology	A branch of medicine concerned with the study, prevention, diagnosis, and management of diseases that affect the liver, gallbladder, biliary tree, and pancreas.

Term	Definition
Nonalcoholic Steatohepatitis ("NASH")	A syndrome that develops in patients who are not alcoholic that causes liver damage that is histologically indistinguishable from alcoholic hepatitis.
New Drug Application ("NDA")	The vehicle through which drug sponsors formally propose that the FDA approve a new pharmaceutical for sale and marketing in the U.S.
Obeticholic Acid	The technical name for Ocaliva.
Ocaliva ("OCA")	Intercept's primary asset. It is a prescription medicine used for the treatment of primary biliary cholangitis (PBC) in adult patients. Also known as OCA or obeticholic acid.
Periodic Safety Update Reports ("PSUR")	Reports providing an evaluation of the benefit-risk balance of a medicine, prepared by pharmaceutical companies.
Pharmacovigilance	The practice of monitoring the effects of medical drugs after they have been licensed for use, especially to identify and evaluate previously unreported adverse reactions.
Primary Biliary Cholangitis ("PBC")	A chronic disease in which the bile ducts in your liver are slowly destroyed.
Pruritus	Localized or generalized itching due to irritation of sensory nerve endings.
Specialty Pharmacy	Drug distribution channel designed to handle specialty drugs that have a higher degree of complexity in terms of distribution, administration, or patient management .

CHRONOLOGY

Date	Event
Aug. 2015	Intercept submits its New Drug Application for Ocaliva as a treatment for patients with primary biliary cholangitis.
Apr. 7, 2016	The FDA holds an Advisory Committee Meeting to discuss potential approval of the drug. The Committee votes to approve the drug.
May 27, 2016	The FDA approves Ocaliva for the treatment of PBC in two different dosing methods. Early-stage PBC patients are to take a daily dose of Ocaliva whereas late-stage PBC patients are to take a weekly dose.
June 9, 2016	Intercept shows a PowerPoint slide that makes a false and/or misleading statement about patient compliance with the Ocaliva dosing regimen. ¶93.
June 24, 2016	The first case of serious liver injury associated with Ocaliva use is reported to Intercept.
Aug. 2016	The first patient is misdosed who later became a subject of the FDA's Safety Announcement.
Aug. 9, 2016	Intercept publishes misleading risk factors in its quarterly financial report for the second quarter of 2016 ("2Q 2016 10-Q"). ¶107.
Aug. 26, 2016	The second patient is misdosed who later became a subject of the FDA's Safety Announcement.
Sept. 1, 2016	The second case of serious liver injury associated with Ocaliva use is reported to Intercept.
Sept. 13, 2016	McMinn makes false and/or misleading statement about patient compliance with the Ocaliva dosing regimen. ¶96. Pruzanski makes false and/or misleading statement about the potential side effects of Ocaliva. ¶115.
Oct. 2016	The third patient is misdosed who later became a subject of the FDA's Safety Announcement.
Oct. 6, 2016	The third case of serious liver injury associated with Ocaliva use is reported to Intercept.
Oct. 10, 2016	The fourth patient is misdosed who later became a subject of the FDA's Safety Announcement.
Oct. 20, 2016	The first two deaths associated with Ocaliva use are reported to Intercept.
Nov. 3, 2016	Intercept repeats PowerPoint slide that makes a false and/or misleading statement about patient compliance with the Ocaliva dosing regimen. ¶¶93, 95.
Nov. 3, 2016	The fifth patient is misdosed who later became a subject of the FDA's Safety Announcement.
Nov. 9, 2016	Intercept's quarterly financial report for the third quarter of 2017 repeats the misleading risk factors set forth in its 2Q 2016 10-Q. ¶109.

Date	Event
Nov. 10, 2016	The third death associated with Ocaliva use is reported to Intercept.
Dec. 5, 2016	Leerink analyst relays false and/or misleading statement made by Intercept regarding potential side effects of Ocaliva. ¶131.
Dec. 9, 2016	The sixth patient is misdosed who later became a subject of the FDA's Safety Announcement.
Dec. 27, 2016	The fourth death associated with Ocaliva use is reported to Intercept.
Prior to Jan. 2017	The seventh patient is misdosed who later became a subject of the FDA's Safety Announcement.
Jan. 4, 2017	The fourth case of serious liver injury associated with Ocaliva use is reported to Intercept.
Jan. 11, 2017	The fifth death associated with Ocaliva use is reported to Intercept.
Jan. 11, 2017	Pruzanski makes false and/or misleading statement about the potential side effects of Ocaliva. ¶119.
Jan. 12, 2017	Intercept repeats PowerPoint slide that makes a false and/or misleading statement about patient compliance with the Ocaliva dosing regimen. ¶¶93, 95.
Jan. 30, 2017	The sixth death associated with Ocaliva use is reported to Intercept.
Feb. 2017	The eighth and ninth patients are misdosed who later became subjects of the FDA's Safety Announcement.
Feb. 1, 2017	The seventh death associated with Ocaliva use is reported to Intercept.
Feb. 18, 2017	The tenth patient is misdosed who later became a subject of the FDA's Safety Announcement.
Feb. 23, 2017	Kim makes false and/or misleading statements about patient compliance with the Ocaliva dosing regimen (¶98) and the potential side effects of Ocaliva (¶121).
Feb. 23, 2017	Intercept repeats PowerPoint slide that makes a false and/or misleading statement about patient compliance with the Ocaliva dosing regimen. ¶¶93, 95.
Feb. 23, 2017	RBC Capital analyst relays false and/or misleading statement made by Intercept regarding potential side effects of Ocaliva. ¶133.
Mar. 2017	The eleventh patient is misdosed who later became a subject of the FDA's Safety Announcement.
Mar. 1, 2017	Intercept's annual report for the year ended Dec. 31, 2016 repeats the misleading risk factors set forth in its 2Q 2016 10-Q. ¶110.
Mar. 7, 2017	The fifth case of serious liver injury associated with Ocaliva use is reported to Intercept.
Mar. 10, 2017	The sixth case of serious liver injury associated with Ocaliva use is reported to Intercept.

Date	Event
Mar. 16, 2017	The eighth death associated with Ocaliva use is reported to Intercept.
Apr. 2017	The twelfth patient is misdosed who later became a subject of the FDA's Safety Announcement.
Apr. 6, 2017	The ninth death and seventh case of serious liver injury associated with Ocaliva use was reported to Intercept.
Apr. 7, 2017	The tenth death associated with Ocaliva use is reported to Intercept.
Apr. 10, 2017	The eleventh death associated with Ocaliva use is reported to Intercept.
Apr. 13, 2017	The eighth case of serious liver injury associated with Ocaliva use is reported to Intercept.
Apr. 20, 2017	The twelfth death associated with Ocaliva use is reported to Intercept.
May 3, 2017	The thirteenth death associated with Ocaliva use is reported to Intercept.
May 4, 2017	Intercept repeats PowerPoint slide that makes a false and/or misleading statement about patient compliance with the Ocaliva dosing regimen. ¶¶93, 95.
May 4, 2017	Kim makes false and/or misleading statement about the potential side effects of Ocaliva. ¶123.
May 10, 2017	Intercept's quarterly financial report for the first quarter of 2017 repeats the misleading risk factors set forth in its 2Q 2016 10-Q. ¶111.
May 11, 2017	The fourteenth death associated with Ocaliva use is reported to Intercept.
May 17, 2017	Pruzanski makes a false and/or misleading statement about patient compliance with the Ocaliva dosing regimen. ¶100.
June 6, 2017	Intercept repeats PowerPoint slide that makes a false and/or misleading statement about patient compliance with the Ocaliva dosing regimen. ¶¶93, 95.
June 9, 2017	The fifteenth death associated with Ocaliva use is reported to Intercept.
June 12, 2017	The ninth case of serious liver injury associated with Ocaliva use is reported to Intercept.
June 12, 2017	Cowen & Co. analyst relays false and/or misleading statement made by Intercept regarding potential side effects of Ocaliva. ¶135.
June 16, 2017	The sixteenth death and tenth case of serious liver injury associated with Ocaliva use are reported to Intercept.
June 20, 2017	The seventeenth death associated with Ocaliva use is reported to Intercept.
June 27, 2017	The eighteenth death and eleventh case of serious liver injury associated with Ocaliva use are reported to Intercept.
June 30, 2017	The nineteenth death associated with Ocaliva use was reported to Intercept.
July 31, 2017	Intercept announces a single patient death due to acute renal and liver failure in its Phase II CONTROL trial.

Date	Event
July 31, 2017	Kim makes false and/or misleading statement about the potential side effects of Ocaliva. ¶123. During the same presentation, Intercept shows a PowerPoint slide that repeats its false and/or misleading statement about patient compliance with the Ocaliva dosing regimen (¶93) and new false and/or misleading statement about the potential side effects of Ocaliva (¶125).
Aug. 2017	The FDA conducts a 13-month review of the safety database for Ocaliva.
Aug. 3, 2017	Intercept's quarterly financial report for the second quarter of 2017 repeats the misleading risk factors set forth in the 2Q 2016 10-Q. ¶112.
Aug. 16, 2017	Pruzanski makes a false and/or misleading statement about patient compliance with the Ocaliva dosing regimen. ¶104.
Sept. 6, 2017	A member of Intercept's management team makes a false and/or misleading statement about patient compliance with the Ocaliva dosing regimen. ¶106.
Sept. 12, 2017,	The Company posts a "Dear Healthcare Provider" Letter warning about the danger of prescribing too much Ocaliva to patients with late-stage PBC.
Sept. 12, 2017	Pruzanski makes false and/or misleading statement about the potential side effects of Ocaliva. ¶144.
Sept. 12, 2017	A UBS analyst relays false and/or misleading statement made by Intercept regarding potential side effects of Ocaliva. ¶146.
Sept. 13, 2017	Intercept's common stock fell $22.73 per share from a close of $113.48 per share on September 11, 2017 to a close of $90.75 per share on September 13, 2017, a drop of approximately 20%.
Sept. 18, 2017	A BMO analyst relays false and/or misleading statement made by Intercept regarding potential side effects of Ocaliva. ¶148.
Sept. 20, 2017	The last day of the Class Period.
Sept. 21, 2017	FDA issues a Safety Alert entitled, "Ocaliva (obeticholic acid): Drug Safety Communication–Increased Risk of Serious Liver Injury", and a corresponding safety announcement, that discloses there were 19 patient deaths, 11 cases of serious liver injury, and 12 cases of incorrect dosing.
Sept. 22, 2017	Intercept's share price fell $36.53 per share, from a close of $98.12 per share on September 20, 2017 to close at $61.59 per share on September 22, 2017, a two-day decline of approximately 37.2%

The allegations in this Amended Class Action Complaint are based on the personal knowledge of Lead Plaintiffs Hou Liu and Amy Fu (together "Lead Plaintiffs")[1] as to Lead Plaintiffs' own acts, and are based upon information and belief as to all other matters alleged herein. Lead Plaintiffs' information and belief is based upon the investigation by Lead Plaintiffs' counsel into the facts and circumstances alleged herein, including: (i) review and analysis of those public filings referenced herein that Intercept Pharmaceuticals, Inc. ("Intercept" or the "Company") made with the United States Securities and Exchange Commission ("SEC"); (ii) review and analysis of those press releases, analyst reports, public statements, news articles, and other publications referenced herein disseminated by or concerning Intercept and the other Individual Defendants named herein (together with Intercept, "Defendants"); (iii) review and analysis of those Company conference calls, press conferences, and related statements and materials referenced herein; (iv) review and analysis of those other documents referenced herein; and (v) communications with confidential witnesses referenced herein. Many additional facts supporting the allegations are known only to Defendants and/or are within their exclusive custody or control. Lead Plaintiffs believe that additional evidentiary support for the allegations will emerge after a reasonable opportunity to conduct discovery.

NATURE AND SUMMARY OF THE ACTION

1. Subject to certain exclusions detailed herein, this is a federal securities class action on behalf of a class consisting of all persons and entities who purchased or otherwise acquired Intercept common stock in the United States or on the NASDAQ Global Select Market from June 9, 2016 through September 20, 2017, both dates inclusive (the "**Class Period**"), seeking to recover damages caused by Defendants' violations of the federal securities laws and

[1] All emphases are added to quotations and all internal citations and internal quotations are omitted unless otherwise noted.

to pursue remedies under Sections 10(b) and 20(a) of the Securities Exchange Act of 1934 (the "Exchange Act") and Rule 10b-5 promulgated thereunder, against the Company and certain of its top executives.

2. Intercept is a pharmaceutical company that manufactures and markets biopharmaceutical products to treat chronic liver diseases utilizing proprietary bile acid chemistry. Founded in 2002, the Company is headquartered in New York, New York. Intercept's stock trades on the NASDAQ Global Select Market under the ticker symbol "ICPT."

3. Intercept's leading pharmaceutical candidate is a drug known as Ocaliva® a/k/a OCA or obeticholic acid ("**Ocaliva**").

4. Intercept developed Ocaliva for the treatment of Primary Biliary Cholangitis ("**PBC**"), a chronic autoimmune disease in which the bile ducts in the liver are slowly destroyed over the course of many years. PBC is categorized into two basic phases based on disease progression: (1) early-stage PBC, where the patient has mild liver injury (a/k/a hepatic injury); and (2) late-stage PBC where the patient has moderate or severe liver injury.[2]

5. On May 31, 2016, Intercept announced that the U.S. Food and Drug Administration ("**FDA**") had granted accelerated approval of Ocaliva for the treatment of patients with PBC. As part of this accelerated approval, and based upon the safety profile of the drug observed during clinical trials, the FDA directed Intercept to closely monitor all adverse events, specifically the serious adverse events of liver injury and death.[3] Under the dosage

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[2] Patients can also be classified as having moderate-stage PBC. *See* Ruby Mehta, *Clinical Review*, FDA 26 (Apr. 22, 2016). For the purposes of labeling Ocaliva, Intercept and the FDA included moderate stage PBC patients in their definition of late-stage PBC in order to only have two classifications of the disease. *See* Amy G. Egan, *Labeling*, Center for Drug Evaluation and Research (May 27, 2016). The complaint has adopted this nomenclature.

[3] The FDA defines an "adverse event" as "any untoward medical occurrence associated with the use of a drug in humans, whether or not considered drug related." IND Safety

regimen approved by the FDA (because they have compromised livers and thus are more vulnerable to drug toxicity) patients with late-stage PBC were to receive only a once-weekly dose of Ocaliva, rather than the once-daily dose approved for patients with early-stage PBC. The FDA also instructed Intercept to monitor patient dosage and ensure that patients received the proper amount of Ocaliva based on their stage of PBC.

6. Based on the enthusiasm generated by the commercial launch of Ocaliva, on or around June 30, 2016, Intercept conducted a public offering of convertible senior notes, raising approximately $447.7 million.

7. However, Ocaliva's launch was flawed from the get-go. In contravention of the FDA's approved dosing regimen, Intercept created a prescription enrollment form that only permitted doctors to request prescriptions for the daily dose of Ocaliva. Even though the form requested that doctors provide information regarding the patients' stage of liver disease, Intercept did not review the form to ensure the accuracy of the requested dose before sending the prescription to one of its specialty pharmacies to be filled.

8. While Intercept was causing patients with late-stage PBC to be misdosed by indiscriminately prescribing the daily dose to every patient, Defendants also had the ability to monitor patients' compliance with the dosing regimen for Ocaliva. The information from every prescription enrollment form that would have indicated a patient's stage of PBC and the dose the patient received was entered into the Company's internal system called Interconnect. Intercept further monitored dosing through its centralized specialty pharmacies and through receipt of

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Reporting, 21 C.F.R. § 312.21 (2017). An adverse event is "serious" if "in the view of either the investigator or sponsor, it results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect." *Id.*

adverse event reports, both of which gave it insight into the dose of Ocaliva that patients were receiving.

9. Intercept also monitored the tolerability of Ocaliva through its FDA-required pharmacovigilance efforts, pursuant to which Intercept submitted adverse event reports to the FDA based upon the adverse event information it received directly from healthcare providers and patients. As part of the Interconnect system, Intercept assigned personalized Care Coordinators to communicate directly with patients to also ensure that they were tolerating Ocaliva.

10. Based on its direct line of sight into prescription data and safety reports, throughout the Class Period, Defendants and other Company executives assured the market that ***patients were tolerating Ocaliva and complying with its dosing regimen.*** For instance, on several occasions during the Class Period, Defendants stated that there were no "***no big surprises***" and that Ocaliva was "***easily tolerated***", when referring to the drug's safety performance. Defendants made these statements on conference calls, in public filings, and to analysts.

11. These statements were materially false and/or misleading when made because Defendants knew, or were reckless in not knowing, that over the course of the Class Period, the Company caused late-stage PBC patients to receive the improper dose of Ocaliva because the Company created and used a prescription enrollment form that only permitted enrollment in the daily dose of Ocaliva. This was especially dangerous because the FDA had repeatedly warned the Company that late-stage PBC patients have compromised livers and are thus more vulnerable to potential drug toxicity. Defendants also knew, or were reckless in not knowing, that adverse event reports received by Intercept showed that patients taking Ocaliva experienced at least ***19 deaths and 11 cases of liver injury*** over the course of 13 months, which indicated that Ocaliva

was associated with an increased risk of serious liver injury and death ("**Potential Side Effects**"). Furthermore, at least ***12 of these patients were prescribed excessive amounts of Ocaliva***, which also indicated that patients' non-compliance with the dosing regimen was potentially causing injury. Contrary to Defendants' positive assertions, these events comprised ***42 red flags*** that would have shocked investors and patients alike.

12. Furthermore, Defendants knew that these events were material. Prior to approving Ocaliva, the FDA repeatedly warned the Company to be mindful of hepatic adverse events and of over-dosing patients with late-stage PBC. During the many years of clinical trials preceding FDA approval of Ocaliva, there were 2 recorded deaths in PBC patients of the 1,325 patients that were exposed to Ocaliva. By the end of June 2017, there were 19 recorded deaths when fewer than 3,000 patients had been exposed to Ocaliva.

13. By August 2017, Intercept could no longer hide the truth. The FDA had conducted a 13-month review of the safety database for Ocaliva and was alarmed by its findings. As a result, on September 12, 2017, the Company published a letter to healthcare providers warning of the danger of prescribing too much Ocaliva to patients (the "**Dear Healthcare Provider Letter**"). *See* Ex. D attached hereto. The letter advised that "[l]iver injury, liver decompensation, liver failure, and death have been reported in patients with moderate to severe hepatic impairment when OCALIVA was dosed more frequently than recommended in labeling for such patients."

14. Because the Company had never once mentioned that patients taking Ocaliva were dying, experiencing liver injury, or being improperly dosed, the market was shocked. As a direct result, Intercept's common stock fell $22.73 per share from a close of $113.48 per share on September 11, 2017 to a close of $90.75 per share on September 13, 2017, a drop of

approximately 20%.

15. Over the next two weeks, Defendants downplayed the warnings in the letter, failing to mention the precise number of deaths and liver injuries, and painting the cases mentioned in the letter as insignificant dosing errors. Unfortunately, the problem was much more serious than Defendants had led the market to believe.

16. On September 21, 2017, the FDA issued a Safety Alert and a Safety Announcement warning doctors about reports of multiple deaths and serious liver injury linked to the drug. The Safety Announcement stated, in relevant part:

- There were 19 deaths associated with Ocaliva use;
- There were 11 cases of serious liver injury associated with Ocaliva use, 5 of which were experienced by early-stage PBC patients;
- There were 12 patients who received the wrong dose of Ocaliva, all of whom had late-stage PBC and received a dose exceeding 7 times the recommended dose of Ocaliva; and
- There were patients that received the correct dose of Ocaliva yet still experienced liver damage.

17. As a result, Intercept's share price fell $36.53 per share, from a close of $98.12 per share on September 20, 2017 to close at $61.59 per share on September 22, 2017, a two-day decline of approximately 37.2%.

18. Throughout the Class Period, Defendants made materially false and/or misleading statements regarding patients' tolerability of and compliance with the dosing regimen of Ocaliva. Due to Defendants' fraudulent acts, statements, and omissions which led to the precipitous decline in the market value of the Company's stock when the truth was revealed, Lead Plaintiffs and other Class members suffered significant damages.

JURISDICTION AND VENUE

19. This action arises under and pursuant to Sections 10(b) and 20(a) of the Exchange Act, (15 U.S.C. §§ 78j(b), 78t(a)), and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5).

20. This Court has jurisdiction over the action pursuant to Section 27 of the Exchange Act (15 U.S.C. § 78aa) and 28 U.S.C. § 1331.

21. Venue is proper in this District pursuant to § 27 of the Exchange Act, 15 U.S.C. § 78aa and 28 U.S.C. § 1391(b), as Intercept's principal place of business is located in this District and certain of the acts and conduct complained of herein, including dissemination or omission of materially false and misleading information to the investing public, occurred in this District.

22. In connection with the acts alleged in this Complaint, Defendants, directly or indirectly, used the means and instrumentalities of interstate commerce, including, but not limited to, the mails, interstate telephone communications, the Internet, and the facilities of the national securities markets.

THE PARTIES

23. Lead Plaintiffs Hou Liu and Amy Fu purchased Intercept common stock at artificially inflated prices during the Class Period and were damaged thereby when the truth was revealed. *See* ECF No. 16-2.

24. Defendant Intercept is incorporated in Delaware and has its principal executive offices located at 10 Hudson Yards, 37th Floor, New York, NY 10001.

25. During the Class Period, Intercept stock traded on the NASDAQ Global Select Market exchange under the ticker symbol "ICPT."

26. Defendant Mark Pruzanski ("**Pruzanski**") founded and at all relevant times has served as the Company's Chief Executive Officer ("**CEO**"), President and Director. Over the

course the Class Period, Pruzanski sold 15% of his shares of Intercept common stock for total proceeds of approximately $12.8 million. Intercept Ownership Information, SEC, *available at* https://www.sec.gov/cgi-bin/own-disp?action=getissuer&CIK=0001270073&type=&dateb=&owner=include&start=160 (last visited July 31, 2018).

27. Defendant Sandip Kapadia ("**Kapadia**") has served at all relevant times as the Company's Chief Financial Officer ("**CFO**").

28. Defendant Richard Kim ("**Kim**") served as the Senior Vice President of Commercial U.S. during the Class Period. He currently serves as the President of U.S. Commercial & Strategic Marketing.

29. Defendant Rachel McMinn ("**McMinn**") served as the Chief Business and Strategy Office from March 2015 until December 31, 2017. During the Class Period, McMinn sold 11% of her shares of Intercept common stock for total proceeds of approximately $223,000. *See id.*

SUBSTANTIVE ALLEGATIONS

A. The Company And Its Business

30. Intercept is a biopharmaceutical company focused on developing and marketing drugs for patients with liver diseases. Intercept Pharmaceuticals, Inc., Annual Report (Form 10-K), 1 (Feb. 28, 2018).

31. Intercept's lead product is Ocaliva, which has been approved by the FDA to treat PBC. *Id.* Intercept is also testing Ocaliva for the treatment of Nonalcoholic Steatohepatitis ("**NASH**") for which the Company conducted a Phase II clinical trial known as the CONTROL trial. *Id.*

32. PBC is a chronic autoimmune disease in which the bile ducts in the patient's liver are slowly destroyed. *See* Mayo Clinic Staff, *Primary biliary cholangitis* (Mar. 9, 2018),

available at https://www.mayoclinic.org/ diseases-conditions/primary-biliary-cholangitis-pbc/symptoms-causes/syc-20376874. PBC is a long-lasting disease that progresses over the course of many years (often decades), and eventually results in death if left untreated. *Id.*

33. PBC classification—either as early-stage or late stage—is determined by the amount of liver damage, a/k/a hepatic impairment, present in the patient. *See* Jesse M. Civan, M.D., *Primary Biliary Cholangitis (PBC)*, Merck Manual (February 2018), *available at* https://www.merckmanuals.com/professional/ hepatic-and-biliary-disorders/fibrosis-and-cirrhosis/primary-biliary-cholangitis-pbc. As liver damage progresses, and fibrosis (*i.e.*, scar tissue) builds up in the liver, the patient develops cirrhosis, which is late-stage liver disease. *See* François Durand & Dominique Valla, *Assessment of the prognosis of cirrhosis: Child-Pugh versus MELD*, 42 J. Hep. S100 (2004). The severity of a patient's cirrhosis is measured by the Child-Pugh scoring system, with three levels from A (least severe) to C (most severe). *See id.*

34. During the approval process for Ocaliva, the FDA and Intercept agreed to define early-stage PBC as those patents where one of the following is present: (1) no or mild hepatic impairment; (2) non-cirrhotic liver damage; (3) or Child-Pugh A cirrhosis. *See* Amy G. Egan, *Labeling*, Center for Drug Evaluation and Research (May 27, 2016). Late-stage PBC is defined as those patients where one of the following is present: (1) moderate or severe hepatic impairment; or (2) Child-Pugh B or C cirrhosis.[4]

B. The FDA And Drug-Induced Liver Injury

35. Doctors can measure whether liver injury has occurred by, *inter alia*, testing a patient's blood for elevations in the following liver enzymes which are leaked from injured liver cells: alanine amino transferase ("**ALT**"), aspartate aminotransferase ("**AST**"), and alkaline

[4] For purposes of this complaint, Lead Plaintiffs have adopted the two stages used for dosing of Ocaliva to classify early-stage and late-stage PBC.

phosphatase ("**ALP**"). *See* Guidance For Industry: Drug-Induced Liver Injury: Premarketing *Clinical Evaluation*, FDA, 8 (2009); *see also* UCSD Lab Medicine, Laboratory Diagnosis of Liver Disease (Spring 2010), *available at* http://ucsdlabmed.wikidot.com/chapter-12. Doctors also test a patient's blood for elevations in the compound bilirubin, which is a waste product that is processed by the liver. *See id.*

36. Liver injury is a primary concern for the FDA; therefore, the agency requires that pharmaceutical companies closely monitor adverse events related to liver function to determine whether any patients are experiencing liver injury. *See* FDA, *Guidance For Industry: Drug-Induced Liver Injury: Premarketing Clinical Evaluation*, 8 (2009). According to the FDA, liver injury has been ***the most frequent single cause of safety-related drug marketing withdrawals for the past 50 years***. *Id*. at 2.

37. Since 2006, the FDA has taken preventive safety actions at least eight times when a drug has been linked to serious liver injury. *See* Liver Injury Appendix attached as Exhibit A hereto. For example, on January 14, 2011, the FDA issued a safety alert warning of cases of severe liver injury caused by Dronedarone. *See* Press Release: FDA, *FDA Drug Safety Communication: Severe liver injury associated with the use of dronedarone (marketed as Multaq)* (Jan. 14, 2011). The FDA stated that it received "several case reports of hepatocellular liver injury and hepatic failure . . . including two post-marketing reports of acute hepatic failure requiring transplantation." *Id.* From July 2009 to October 2010, 429,000 Dronedarone prescriptions were dispensed. *Id*. Therefore, pharmaceutical companies, particularly those in the hepatology space like Intercept, are aware that ***the FDA will act at the very first signs of possible drug-induced liver injury***.

38. One of the reasons that the FDA takes liver injury so seriously is that even the first signs of injury have the potential to drastically change the benefit-risk profile of a drug. Before approving a drug, the FDA conducts a benefit-risk analysis:

> [F]or a drug to be approved for marketing, ***FDA must determine that the drug is effective and that its expected benefits outweigh its potential risks to patients.*** This assessment is informed by an extensive body of evidence about the drug's safety and efficacy submitted by an applicant in a New Drug Application (NDA) or Biologics Licensing Application (BLA). This assessment is also informed by a number of other factors, including: ***the severity of the underlying condition and how well patients' medical needs are addressed by currently available therapies; uncertainty about how the premarket clinical trial evidence will extrapolate to real-world use of the product in the postmarket setting; and whether risk management tools are necessary to manage specific risks***.

FDA, *Benefit-Risk Assessment in Drug Regulatory Decision-Making*, 2 (Mar. 30, 2018), *available at* https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM602885.pdf. When the risks of a drug outweigh the benefits, the FDA may impose restrictions on use of the drug or withdraw the drug from use altogether. *See, e.g.*, *FDA Seeks Withdrawal of Endo's Opana ER, Citing Opioid Risks*, Genetic Engineering & Biology News (June 9, 2017), https://www.genengnews.com/gen-news-highlights/fda-seeks-withdrawal-of-endos-opana-er-citing-opioid-risks/81254479.

C. The FDA Grants Accelerated Approval Of Ocaliva For The Treatment Of Primary Biliary Cholangitis

39. In August 2015, the FDA accepted Intercept's New Drug Application ("**NDA**") for Ocaliva as a treatment of patients with PBC who have an inadequate response to, or are intolerant of, Ursodiol (a/k/a Urso or UDCA), the current standard of care for PBC. Press Release: Intercept Pharmaceuticals, Inc., *FDA Grants Priority Review for Intercept's Obeticholic Acid for the Treatment of Primary Biliary Cirrhosis* (Aug. 31, 2015).

40. As part of its NDA package, Intercept disclosed that 2 patients with PBC died during all the clinical trials in which 1,325 people were exposed to Ocaliva, and the most

common side effect was pruritus, which is a localized or generalized itching of the skin due to irritation of sensory nerve endings. *See* Ruby Mehta, MD, *Clinical Review*, FDA, 17, 201, 212 (Apr. 22, 2016).

1. The FDA's Pre-Approval Comments

41. After reviewing the NDA for Ocaliva, the FDA held an Advisory Committee Meeting on April 7, 2016 to discuss potential approval of the drug. *See* Transcript of the Gastrointestinal Drugs Advisory Committee Meeting, FDA (Apr. 7, 2016) ("**AC Transcript**"). In advance of the meeting, the FDA provided Intercept and members of the Advisory Committee with a briefing package containing assessments, conclusions, and recommendations written by FDA reviewers. *See* FDA Briefing Package for NDA 207999, FDA (Apr. 7, 2016) ("**Briefing Package**"). Two themes were apparent throughout these documents: (1) because patients with late-stage PBC have more compromised livers, and thus are more vulnerable to drug toxicity, they should take a reduced ***weekly*** dose of Ocaliva; (2) all patients should be closely monitored to ensure they are tolerating Ocaliva.

42. First, because late-stage PBC patients have more compromised livers, and thus are more vulnerable to potential drug toxicity, the FDA and members of the Advisory Committee told Intercept that, in order to prevent injury, these patients should take a lower weekly dose of Ocaliva, instead of the daily dose proposed by Intercept. For example, during the Advisory Committee Meeting, Dhananjay Marathe, the Senior Reviewer in the Division of Pharmaceutics at the FDA's Center for Drug Evaluation and Research, stated that:

> ***[T]he applicant proposed no dose adjustment for any hepatic impairment category***, the rational[e] being that these are modest changes in liver exposure, and any dose adjustment might lead to lower liver exposures, which could be suboptimal for efficacy. Now, ***FDA's position in this regard is that the dose adjustment is desirable, and that is for the following reasons***. . . . [T]here's no clear benefit of such high exposures since the reduction in ALP plateaus at plasma exposures are equivalent to 10-milligram QD dose.

AC Transcript at 179.

43. Second, the FDA expressed concern over the signs of liver injury observed in several patients who received higher doses of Ocaliva in the clinical trials. *See* Briefing Package at 60. Thus, to address this concern, the FDA and the Advisory Committee instructed Intercept to closely monitor patients treated with Ocaliva to detect any serious adverse events like liver injury. For example, the Briefing Package stated that:

> Since most patients enrolled in trial 747-301 were early stage disease, we are unable to assess whether OCA is safe in patients with moderately advanced disease (evidence of loss of hepatic synthetic function) and advanced stage disease (consistent with cirrhosis). ***FDA thinks that it will be important to gather information on safety and efficacy of OCA in patients with moderately advanced disease and advanced disease.***

Briefing Package at132.

2. The FDA's Post-Approval Comments

44. After providing these recommendations, the Advisory Committee voted to approve Ocaliva. *See* AC Transcript. Then, on May 27, 2016, the FDA approved Ocaliva under the FDA's Accelerated Approval Program. *See* Intercept Pharmaceuticals, Annual Report (Form 10-K), 23-24 (Feb. 28, 2018).

45. Accelerated Approval is used for drugs that treat serious diseases and appear to provide a meaningful benefit over available therapy. *See* FDA, *Guidance for Industry: Expedited Programs for Serious Conditions – Drugs and Biologics*, 16 (May 2014). Because pharmaceutical companies do not need to provide as much confirmatory safety data, as a condition of Accelerated Approval, the FDA continues to scrutinize the safety and efficacy of the drug and requires phase 4 post-marketing confirmatory trials. *See id.* at 22. Because Accelerated Approval is granted on an expedited basis, the FDA may withdraw approval if, *inter alia*, evidence demonstrates that the product is not safe. *See id.* at 23.

46. Heeding the advice of the Advisory Committee, the FDA approved Ocaliva in two different dosing increments based upon which stage of PBC the patient was experiencing, utilizing the lowest doses tested in the prior clinical trials. *See also* Amy G. Egan, *Labeling*, FDA, 1-3 (May 27. 2016).

- ***For early-stage PBC patients*** – defined as those patents with no or mild hepatic impairment, non-cirrhotic, or Child-Pugh A cirrhosis – ***dosing shall begin at 5 milligrams once DAILY***, increasing after 3 months to 10 milligrams once daily based upon tolerability and treatment response.

- ***For late-stage PBC patients*** – defined as those with moderate or severe hepatic impairment, Child-Pugh B or C cirrhosis – ***dosing shall begin at 5 milligrams once WEEKLY*** (one seventh the dose exposure of earlier-stage patients), with the possibility after 3 months to increase to 5 milligrams twice weekly based upon tolerability and treatment response, then to gradually increase to a maximum of 10 milligrams twice weekly.

47. As part of approval, the FDA provided Intercept with lengthy memoranda explaining its findings in support of its decision. In these documents, the FDA reiterated its concerns over potential liver injury and the vulnerabilities of patients with late-stage PBC. Echoing the two themes of the Briefing Package and Advisory Committee Meeting, the FDA issued two mandates: (1) late-stage PBC patients must take a reduced weekly dose of Ocaliva; and (2) Intercept must closely monitor all patients to ensure that they are tolerating Ocaliva. *See, e.g.*, Ruby Mehta, MD, *Clinical Review*, FDA (Apr. 22, 2016).

a. The FDA Instructs Intercept that Late-Stage PBC Patients Must Take a Reduced Weekly Dose of Ocaliva

48. First, as a condition of approval, the FDA repeatedly instructed Intercept that it is imperative that late-stage PBC patients take a lower, weekly dose of Ocaliva, instead of a daily dose:

- The Applicant proposed no dose adjustment for hepatic impairment, however, ***the FDA review team recommended a dose reduction in patients with Child Pugh B and C cirrhosis in addition to close patient***

monitoring, which is also included in the labeling. Ruby Mehta, MD, *Clinical Review*, FDA, 17 (Apr. 22, 2016).

- Given the signal of dose-response for pruritus in PBC patients FDA proposed an ***alternative dosing regimen of 5 mg QW (once weekly) as the starting dose to target comparable initial plasma exposures to patients with no or mild hepatic impairment***. . . . It is worth noting that the Applicant had proposed no dose adjustment for hepatic impairment citing that despite higher systemic plasma exposure levels of OCA in patients with hepatic impairment. *Id.* at 41.

- ***It is clear that higher exposures to OCA are associated with increases in serum transaminases and bilirubin*** in both the nonclinical and phase 1 studies. . . . Hepatic related adverse reactions also appear to occur at an increased frequency with increasing dose from the analysis of the combined data from phase 2 and 3 studies. . . . ***Therefore the reduced dose of OCA as recommended by the Clinical Pharmacology team will be recommended in the labeling***. Lara Dimick-Santos, M.D., *Cross-Discipline Team Leader Review*, FDA, 77 (May 27, 2016).

b. The FDA Instructs Intercept To Monitor All Patients To Ensure Ocaliva Is Well Tolerated

49. Second, the FDA again told Intercept that it needs to monitor how patients tolerated Ocaliva by paying close attention to serious adverse events like liver injury:

- ***All patients should be monitored for alterations in liver biochemical tests and development of liver-related adverse reactions.*** Amy Egan, MD, MPH, *Office Deputy Director Decisional Memo*, FDA, 19 (May 26, 2016).

- [L]ower doses should be recommended for patients with hepatic impairment and ***it is important to monitor these patients closely and adjust dose or discontinue treatment for evidence of liver injury.*** Ruby Mehta, MD, *Clinical Review*, FDA, 39 (Apr. 22, 2016).

- [T]he reduced dose of OCA as recommended by the Clinical Pharmacology team will be recommended in the labeling. ***Patients with cirrhosis or advanced stage disease by the Rotterdam criteria should be monitored closely with initiation and during treatment with OCA.*** Lara Dimick-Santos, M.D., *Cross-Discipline Team Leader Review*, FDA, 75 (May 27, 2016).

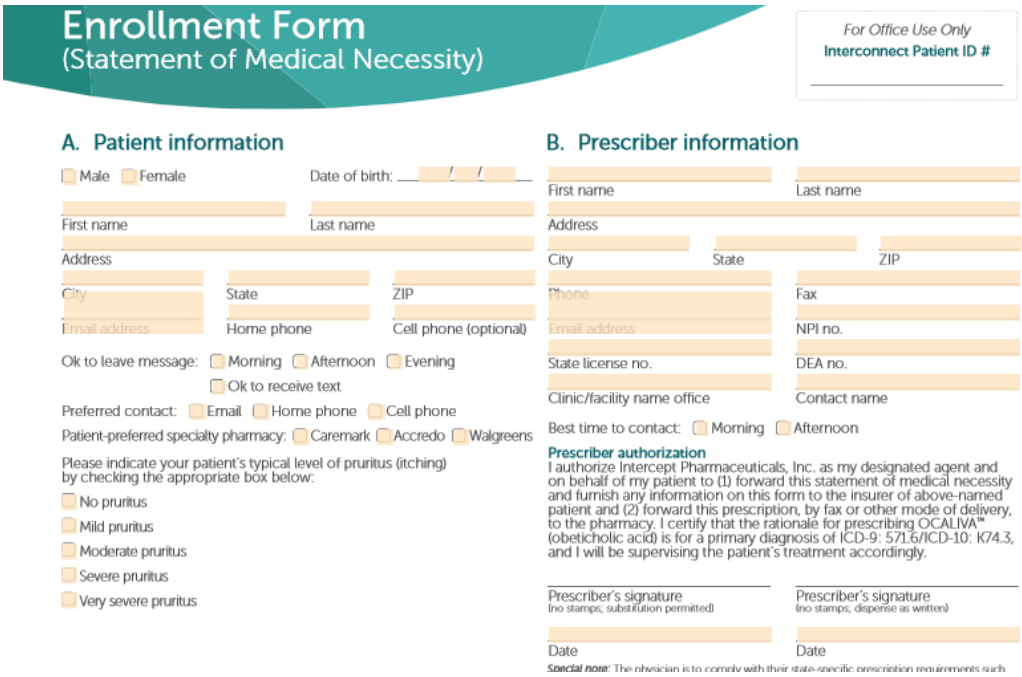
D. Intercept's Enrollment And Prescription Process For Ocaliva

50. Despite the FDA's clear instructions and irrespective of the negative impact on patients' health, during the Class Period, Intercept used an enrollment process and specialty pharmacy system that was likely to result in, and in fact did result in, late-stage PBC patients receiving the incorrect daily dose of Ocaliva.

51. Prior to the launch of Ocaliva, Intercept created an "**online patient services hub**" called "**Interconnect**" through which it facilitated the drug enrollment process.

52. Interconnect was a major selling point for Intercept's launch of Ocaliva because it allowed the Company to, *inter alia*, interact directly with doctors and patients. During the Class Period, Interconnect served three relevant purposes. First, it was a patient help center that used patient Care Coordinators to communicate with patients to gain insight on their experiences on Ocaliva. Second, it was a one-stop prescription shop for doctors that provided the forms and information required to fill prescriptions and access insurance coverage. Third, it was an adverse event reporting system that allowed Intercept to satisfy its FDA reporting duties, as mentioned in ¶52. *See* Rachel McMinn, Presentation at Wedbush PacGrow Healthcare Conference (Aug. 16, 2017) (transcript available through Bloomberg).

53. As a one-stop prescription shop for doctors, Interconnect provided doctors with the forms they needed to send Ocaliva prescriptions directly to Intercept. To prescribe Ocaliva, doctors could access Interconnect via the Internet to obtain the required Ocaliva prescription Enrollment Form (the "**Enrollment Form**"). *See* Ex. B. As noted below, to enroll a patient on Ocaliva, the doctor would first provide basic patient and prescriber information on the Enrollment Form:



Enrollment Form
(Statement of Medical Necessity)

For Office Use Only
Interconnect Patient ID #

A. Patient information

Male Female Date of birth: ___/___/___

First name Last name

Address

City State ZIP

Email address Home phone Cell phone (optional)

Ok to leave message: Morning Afternoon Evening
Ok to receive text

Preferred contact: Email Home phone Cell phone

Patient-preferred specialty pharmacy: Caremark Accredo Walgreens

Please indicate your patient's typical level of pruritus (itching) by checking the appropriate box below:

No pruritus
Mild pruritus
Moderate pruritus
Severe pruritus
Very severe pruritus

B. Prescriber information

First name Last name

Address

City State ZIP

Phone Fax

Email address NPI no.

State license no. DEA no.

Clinic/facility name office Contact name

Best time to contact: Morning Afternoon

Prescriber authorization
I authorize Intercept Pharmaceuticals, Inc. as my designated agent and on behalf of my patient to (1) forward this statement of medical necessity and furnish any information on this form to the insurer of above-named patient and (2) forward this prescription, by fax or other mode of delivery, to the pharmacy. I certify that the rationale for prescribing OCALIVA™ (obeticholic acid) is for a primary diagnosis of ICD-9: 571.6/ICD-10: K74.3, and I will be supervising the patient's treatment accordingly.

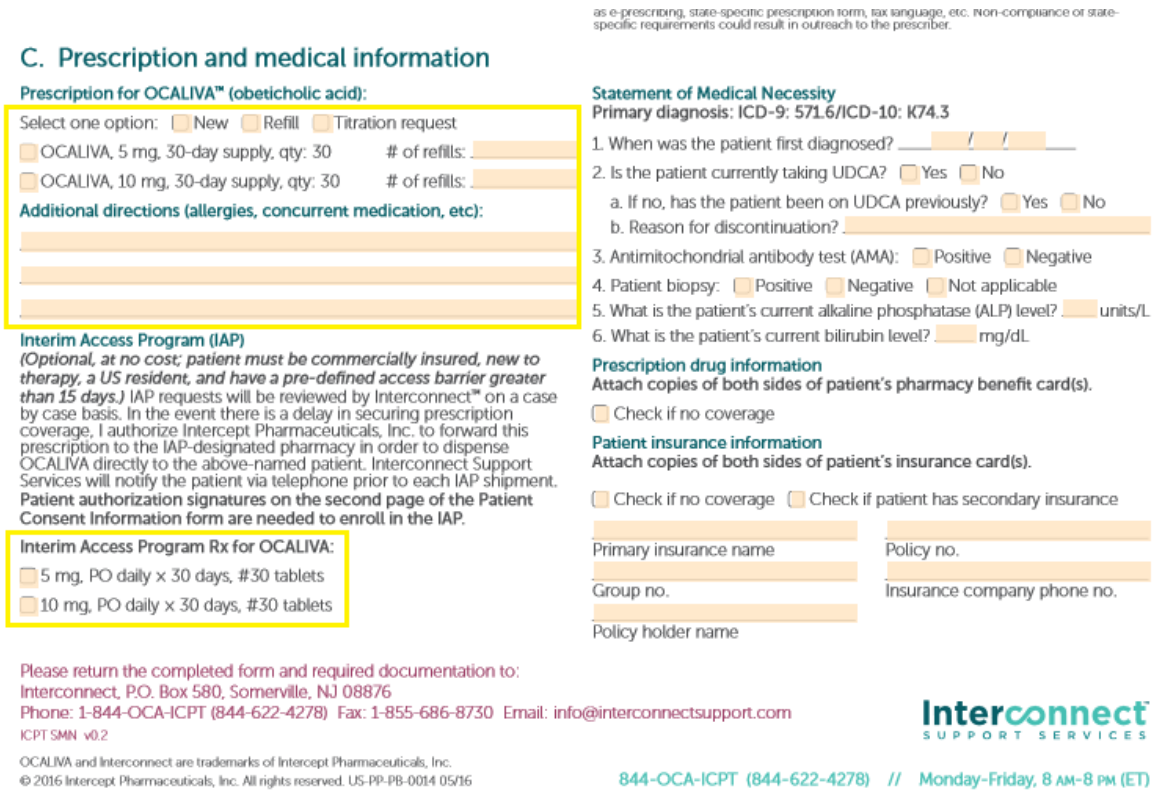
Prescriber's signature (no stamps; substitution permitted) Prescriber's signature (no stamps; dispense as written)

Date Date

Special note: The physician is to comply with their state-specific prescription requirements such

54. The doctor would then select the dosage amount for the prescription. The Enrollment Form only provided the doctor with two dosage options. The first option was "OCALIVA, 5 mg, ***30-day*** supply, qty 30[.]" The second option was OCALIVA, 10 mg, ***30-day*** supply, qty 30[.]" These "***daily***" options were repeated again at the bottom of the form. Importantly, the Enrollment Form ***did not have an option to select a weekly prescription dose*** of Ocaliva:[5]

[5] Lead Plaintiffs have added yellow boxes to the form for the Court's convenience.



as e-prescribing, state-specific prescription form, fax language, etc. Non-compliance of state-specific requirements could result in outreach to the prescriber.

C. Prescription and medical information

Prescription for OCALIVA™ (obeticholic acid):

Select one option: New Refill Titration request

OCALIVA, 5 mg, 30-day supply, qty: 30 # of refills:

OCALIVA, 10 mg, 30-day supply, qty: 30 # of refills:

Additional directions (allergies, concurrent medication, etc):

Interim Access Program (IAP)

(Optional, at no cost; patient must be commercially insured, new to therapy, a US resident, and have a pre-defined access barrier greater than 15 days.) IAP requests will be reviewed by Interconnect™ on a case by case basis. In the event there is a delay in securing prescription coverage, I authorize Intercept Pharmaceuticals, Inc. to forward this prescription to the IAP-designated pharmacy in order to dispense OCALIVA directly to the above-named patient. Interconnect Support Services will notify the patient via telephone prior to each IAP shipment. **Patient authorization signatures on the second page of the Patient Consent Information form are needed to enroll in the IAP.**

Interim Access Program Rx for OCALIVA:

5 mg, PO daily x 30 days, #30 tablets

10 mg, PO daily x 30 days, #30 tablets

Statement of Medical Necessity

Primary diagnosis: ICD-9: 571.6/ICD-10: K74.3

1. When was the patient first diagnosed? ___/___/___
2. Is the patient currently taking UDCA? Yes No
   a. If no, has the patient been on UDCA previously? Yes No
   b. Reason for discontinuation?
3. Antimitochondrial antibody test (AMA): Positive Negative
4. Patient biopsy: Positive Negative Not applicable
5. What is the patient's current alkaline phosphatase (ALP) level? ___ units/L
6. What is the patient's current bilirubin level? ___ mg/dL

Prescription drug information

Attach copies of both sides of patient's pharmacy benefit card(s).

Check if no coverage

Patient insurance information

Attach copies of both sides of patient's insurance card(s).

Check if no coverage Check if patient has secondary insurance

Primary insurance name | Policy no.

Group no. | Insurance company phone no.

Policy holder name

Please return the completed form and required documentation to:
Interconnect, P.O. Box 580, Somerville, NJ 08876
Phone: 1-844-OCA-ICPT (844-622-4278) Fax: 1-855-686-8730 Email: info@interconnectsupport.com
ICPT SMN v0.2

Interconnect SUPPORT SERVICES

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844-OCA-ICPT (844-622-4278) // Monday-Friday, 8 AM-8 PM (ET)

55. This form required doctors to submit certain limited information from which a person with sufficient medical knowledge of hepatic injury could infer the amount of liver damage present in the patient and which stage PBC the patient had. Specifically, the Enrollment Form asked the doctor to note the patient's ALP and bilirubin levels. Because a patient with a bilirubin score over 3 mg most likely has Child-Pugh B or Child-Pugh C, the bilirubin level listed on the form would have indicated whether the patient had late-stage PBC. *See Child-Turcott-Pugh (CTP) Calculator*, Hepatitis C Online, https://www.hepatitisc.uw.edu/page/clinical-calculators/ctp (last visited July 30, 2018).

56. The Enrollment Form was inherently flawed because ***it prevented doctors from selecting the lower weekly dose for patients with late-stage PBC***; thus, the form forced all patients to be prescribed the daily dose of Ocaliva, regardless of their stage of PBC. Notably, the Enrollment Form did not explain the dosing regimen approved by the FDA, and ***no part of the***

Enrollment Form mentioned that the weekly dose ***was even an option*** for patients. *See* the full Enrollment Form attached hereto as Exhibit B.

57. To complete enrollment of a patient and obtain a prescription for Ocaliva, the doctor would then submit the Enrollment Form directly online through Interconnect or by mailing, emailing, or by faxing the form to Intercept. *See* Let's Get Started, Interconnect Support System, https://www.interconnectsupport.com/enrollment-form-intro/ (last visited July 12, 2018).

58. Confidential Witness No. 1 ("**CW1**"), who worked as Medical Director at Intercept at all times during the Class Period,[6] explained that when the Enrollment Form was received by Intercept, an administrative employee would enter the information from the form, including the dose selected and the patient's bilirubin and ALP levels, into Interconnect's central database and then directly transfer a prescription request to one of Intercept's specialty pharmacies. There was no second set of eyes reviewing the form to ensure that the dosage requested was correct before the prescription request was sent to the pharmacy.

59. By using the Enrollment Form and failing to review the dosage requested, Intercept disregarded its FDA-mandated obligation to provide a lower "weekly" dose of Ocaliva to patients with late-stage PBC, and caused these patients to receive an incorrect, grossly excessive amount (7x) of Ocaliva.

60. After the information from the Enrollment Form was entered into Intercept's central database, Intercept sent a prescription request, which only contained the dose and frequency of Ocaliva, directly to one of Intercept's specialty pharmacies. During the Class Period, Intercept maintained its own centralized system of three specialty pharmacies that

[6] CW1 directly reported to the Vice President of Medical Affairs, Uche Iloeje, who directly reported to Chief Operating Officer, Jerry Durso.

managed all prescriptions and refills for Ocaliva and directly distributed the drug to patients. *See* Mark Pruzanski, Presentation at Goldman Sachs Healthcare Conference (Jun. 8, 2016) (transcript available through Bloomberg). As Intercept's brochure regarding its specialty pharmacies explained: "A specialty pharmacy is different from your neighborhood pharmacy[,]" "[i]t's more like a mail order pharmacy where you have your medicine shipped to you." *See* Exploring the Possibilities, Intercept (2017), *available at* https://ocalivahcp.com/_assets/_pdfs/specialty-pharmacy-brochure.pdf.

61. Thus, this specialty pharmacy system interjected Intercept as the intermediary between the doctor and the pharmacy. Intercept became the point of contact for both parties and controlled the flow of information about Ocaliva, which made it much more difficult for doctors to ensure that their patients were prescribed the correct dose of the drug.

62. For example, CW1 explained that an incident occurred where a doctor treating a late-stage PBC patient selected the daily dose of Ocaliva because it was the only option on the Enrollment Form. However, the doctor was confused by the Enrollment Form and incorrectly expected Intercept to instead provide the weekly dose when it reviewed the form and saw that the patient had a high bilirubin level. Because the employees at Intercept who were tasked with processing the Enrollment Forms were not instructed to review the forms for accuracy, the patient was simply prescribed the daily dose. The doctor was shocked when the patient reported for a check up and explained that he/she had been taking the higher dose of Ocaliva.

63. Also, a PBC patient named Dianne Dennis explained in a Facebook post that Intercept had recommended that she take the incorrect, daily dose of Ocaliva, which led to liver injury:

64. Intercept benefitted handsomely by overdosing certain patients. The Company charged almost $70,000 annually for the 5 mg and 10 mg daily dose of Ocaliva, and approximately $10,000 annually for the weekly dose. Rachel McMinn, Ocaliva Approval Call (May 31, 2016) (Transcript available through Bloomberg Law). Over a one-year period, a patient taking the daily dose of Ocaliva would spend $60,000 more than a patient taking only the weekly dose.

E. Defendants Monitored Patients' Compliance With Ocaliva's Dosing Regimen Through Intercept's Internal Systems

65. While Intercept was already aware or recklessly disregarded that it was causing late-stage PBC patients to be systematically overdosed, the Company was also able to closely track the dose received by all patients.

66. **Interconnect System**: CW1 explained that all of the information from the Enrollment Forms was entered into Intercept's central Interconnect database. Therefore, the bilirubin levels for each patient, which would have indicated whether a patient had late-stage PBC, and what dose of Ocaliva that patient was receiving could have been pulled from the system and reviewed at any time. CW1 stated that Pruzanski would have been able to access this information simply by calling Keith White, the Executive Director of Managed Markets, and requesting a report. In fact, Defendants did pull data from the database during the Class Period to gain insight on the characteristics of the patient population taking Ocaliva. *See* ¶162.

67. **Specialty Pharmacies**: The central pharmacy system controlled by Intercept also allowed Intercept to very closely track the prescriptions that were being filled, and have a direct line of sight into the dosage being taken by patients. Pruzanski explained on a conference call on June 8, 2016, that Intercept's specialty pharmacies would give the Company very accurate, up to date prescription information, stating: "we're distributing through three specialty pharmacies. So after an initial period we do expect IMS data to be relatively accurate."[7]

68. An Intercept officer further explained on a September 6, 2017 call with an analyst at Robert W. Baird & Co., Inc., that Intercept had a great deal of information on each patient taking Ocaliva to ensure that the drug was being prescribed properly and that patients were

[7] "IMS data" refers to data collected by IMS Health, Inc., a company that, *inter alia*, provides information services to the healthcare industry.

tolerating the drug well: "[W]e're also very much focused on is compliance and persistency, right, because this is something that over time is important. And for that we have our patient services hub, and we also have a specialty pharmacy by which we distributed" to accomplish this.

69. **Adverse Event Reporting**: Per 21 C.F.R. § 314.80(f)(3) (explained below), the adverse event reports that Intercept submitted to the FDA during the Class Period were required to include the "[d]ose, frequency, and route of administration used" of the drug and "therapy dates" as well as patient information such as the "[d]iagnosis for use (indication)" for the patient. Thus, by processing and submitting these reports, Intercept would have known the stage of liver disease possessed by the patients who were the subjects of the reports and whether they were receiving the proper dose of Ocaliva.

70. In fact, in many of the adverse event reports that were later the subject of the FDA's Safety Announcement, Intercept ***specifically stated in the "Company comment" section*** of the report that ***the patient was taking the incorrect dose*** of the drug based upon the severity of the patient's liver disease. *See* SAE Chart below, ¶86.

F. Intercept Monitored Patients' Tolerance Of Ocaliva Through Its Adverse Event Reporting Duties And Its Interconnect System

71. In addition to monitoring how its patients complied with Ocaliva's dosing regimen, Intercept monitored how its patients tolerated Ocaliva. Specifically, the Company took note of all adverse events, pursuant to a statutory duty of pharmacovigilance and a specific FDA-imposed duty as a condition of Ocaliva's approval.

1. Intercept Had a Duty To Monitor the Tolerance of Ocaliva Through Pharmacovigilance

72. Any time a drug is being tested on human subjects, the FDA requires that pharmaceutical companies conduct pharmacovigilance monitoring. Pharmacovigilance is a term

that describes "all scientific and data gathering activities relating to the detection, assessment, and understanding of adverse events." *See* FDA, *Guidance for Industry: Good Pharmacovigilance Practices and Pharmacoepidemiologic Assessment*, 4 (2005). "These activities are undertaken with the goal of identifying adverse events and understanding, to the extent possible, their nature, frequency, and potential risk factors." *Id.*

73. This principally involves the "identification and evaluation of safety signals," or "an excess of adverse events compared to what would be expected to be associated with a product's use." *Id.* The FDA highlights the fact that, "***even a single well documented case report can be viewed as a signal, particularly if the report describes a positive rechallenge or if the event is extremely rare in the absence of drug use***." *Id.*

74. When an adverse event occurs while a patient is taking a drug, the healthcare professionals treating the patient submit a report to either the company marketing the drug and/or to the FDA explaining the event. Federal law requires that when a drug company receives an adverse event report from a healthcare professional or other third party, the company (a/k/a the applicant), "must promptly review all adverse drug experience information obtained or otherwise received by the applicant from any source, foreign or domestic," and, "submit to FDA adverse drug experience information[.]" Post Marketing Reporting of Adverse Drug Experiences, 21 C.F.R. § 314.80(b), (c) & (f) (2017).

75. The company is required to "report each adverse drug experience that is both serious and unexpected, whether foreign or domestic, as soon as possible but no later than 15 calendar days from initial receipt of the information by the applicant[,]" to the FDA and each adverse drug experience that is not serious or unexpected "at quarterly intervals, for 3 years from the date of approval of the application, and then at annual intervals" to the FDA. 21 C.F.R. §

314.80(c)(1)(i) & (c)(2). Every adverse event report should include a detailed narrative of the event, including information regarding the patient's medical history, dosage of the drug, the start and stop dates for the drug, concomitant medications, lab test results, outcomes attributed to the drug, and a description of the adverse event experience. 21 C.F.R. § 314.80(f).

76. The process of gathering and analyzing the adverse event information and preparing the adverse event reports for the FDA is typically conducted by the pharmacovigilance department within a drug company. *See* Suzanne Gagone, et al., *Pharmacovigilance and Risk Management in* Global Clinical Trials Playbook 141, 143-144 (Menghis Bairu & Richard Chin eds. 2012).

77. As required by federal regulation, Intercept had a pharmacovigilance department. *See* Careers: Sr. Associate, Pharmacovigilance, Intercept Pharmaceuticals, Inc. (July 11, 2018), https://www.interceptpharma.com/career/sr-associate-pharmacovigilance/. This department processed and assessed adverse event reports, and then aggregated the safety information obtained from the reports into a central system so that it could identify any emerging safety signals. *See id.* The majority of the adverse event information was provided to Intercept via its online Interconnect system, where healthcare providers could write directly to the Company and the Company could easily obtain follow up information from these parties. *See For Healthcare Professionals*, Interconnect Support Services, https://www.interconnectsupport.com/for-healthcare-professionals (last visited July 31, 2018). Pruzanksi also explained during the Class Period that Intercept maintained "***a very extensive safety database***" from which it could analyze the safety data for Ocaliva. Mark Pruzanski, Presentation at RBC Capital Markets Health Care Conference (Feb. 23, 2017); *see also* Mark Pruzanski, Presentation at J.P. Morgan Health Care

Conference (Jan. 11, 2017) ("[W]e have a very extensive safety database with over 675 patient years of exposure in our first indication alone.").

2. Intercept Had a Duty to Monitor the Tolerance of Ocaliva as a Condition of Approval

78. Prior to Ocaliva's approval, the FDA repeatedly told Intercept in its Briefing Package, at its Advisory Committee Meeting, in the approval memoranda, and likely during confidential meetings, that Intercept would need to closely monitor patients taking Ocaliva for any signs of hepatic injury. *See* ¶¶41-43.

79. Indeed, the FDA was so concerned over the potential of Ocaliva to cause liver injury in patients with late-stage PBC that, as a condition of approval, Intercept was required to conduct a phase IV trial for patients with late-stage PBC to further evaluate the safety of the drug. *See* Amy G. Egan, M.D., M.P.H., *Ocaliva Approval Letter* 2 (May 27, 2016). If this phase IV trial fails, or other evidence demonstrates that Ocaliva is not safe for its conditions of use, the FDA can withdraw approval of the drug. *See* ¶¶44-49. Thus, ***monitoring the safety of Ocaliva was vital to Intercept's survival***.

80. Intercept used Interconnect as one way to fulfill its FDA-mandated safety monitoring obligations. As a patient help center, Interconnect provided personal Care Coordinators who furnished ongoing personal support by communicating directly with patients and healthcare providers to, *inter alia*, answer questions and address safety concerns regarding Ocaliva. On May 31, 2016, on a conference call advertising the FDA's approval of Ocaliva, this feature of Interconnect was described in the following way:

> Kim: "***So, yeah, Interconnect, to your point, goes well beyond just helping to support patients through getting their claim sort of reviewed. Interconnect will also have personalized Care Coordinators*** who got – the patients will have the same person throughout their entire course of treatment is our goal, depending on how long it is, of course. But their goal will also be ***call back and provide reminders for their patients***. ***So there will be callbacks every few months to check to see if***

> ***the patients are still on their medications and if they have any questions and, where needed, there are nearest counselors that are available to help answer questions on their medication as well. So we're really committed to Interconnect, really providing very comprehensive services for both the product acquisition and supporting the patients through their journey with Ocaliva as well.***

81. Through these Care Coordinators, Intercept was able to reach out to patients to ensure that they were tolerating their Ocaliva treatment. Interconnect even allowed Intercept to create personalized reminders for patients. Through Interconnect, if a patient failed to refill a prescription, the Company was alerted to check on the patient to ensure that no serious adverse events, like death or liver injury, had occurred. Pruzanski explained that:

> ***[W]e set-up a patient services hub called Interconnect, which I think has done a great job in handholding patients and physicians' offices from the time of scripts to getting patients on drug and beyond***. And I'm very pleased to say that we're now at from writing script to converting patients to drug at around three week, which is very much in keeping with sort of best in class practice . . . Interconnect of course plays a major role . . . ***ensuring that once patients get on drug that they stay on drug if they're able to – if they're tolerating the drug. And so, adherence programs are major area of focus. And what we announced in Q2, we now have some visibility on compliance and persistency***.

Mark Pruzanski, Presentation at Wedbush PacGrow Healthcare Conference (Aug. 16, 2017) (transcript available through Bloomberg Law).

82. This alert feature ***allowed the Company to monitor patients' tolerance*** because any safety concerns would have been reported to the Care Coordinators.

G. Defendants Learn That Patients Were Neither Tolerating Ocaliva Nor Complying With The Proper Dosing Regimen

83. Beginning with the launch of Ocaliva, Intercept used an Enrollment Form that did not permit doctors to select the lower weekly dose of the drug for patients with late-stage PBC. ¶56. While the Enrollment Form did request enough information to indicate whether a patient had late-stage PBC, which was entered into Intercept's internal system and easily accessed by all Defendants, no one at Intercept reviewed the Enrollment Forms to ensure that the dosage was

correct before the prescription request was sent to Intercept's specialty pharmacies to be filled. ¶58. In effect, despite the FDA's repeated warnings, Intercept indiscriminately prescribed the daily dose to all patients, even if they had late-stage of PBC. ¶64.

84. Intercept's faulty Enrollment Form quickly became problematic for the Company. Indeed, within a few months of FDA approval, Intercept began to learn of alarming Potential Side Effects connected to Ocaliva concerning serious liver injury and deaths. The early events were particularly concerning because by June 30, 2016 and July 31, 2016, only 23 and 86 patients, respectively, had been prescribed Ocaliva. *See* IMS Prescription Data for Ocaliva (available through Bloomberg).

85. Events of this nature were eventually flagged in the FDA's Safety Announcement issued on September 21, 2017. ¶150. The events that the FDA noted in its Safety Announcement are chronologically tallied below in the Serious Adverse Event Chart ("**SAE Chart**") in the "SAE Number" column. The chart is based upon information in the adverse event reports Intercept submitted to the FDA as part of its pharmacovigilance responsibilities and which were obtained by Lead Counsel as the result of a request submitted pursuant to the Freedom of Information Act ("**FOIA**"), 5 U.S.C. § 552.

86. As indicated below, by the end of June 2017, the adverse event reports prepared by Intercept showed that patients taking Ocaliva had experienced ***19 deaths and at least 11 cases of serious liver injury***, at a time when fewer than 3,000 patients had taken the drug. *See* Christian Flanagan, *Intercept Down on Death, Cholesterol Concerns in Study*, Bloomberg (Jul. 31, 2017). This number is alarming, especially when compared to the clinical trials of Ocaliva where 2 PBC patients died in pool of 1,325 patients. *See* Ruby Mehta, MD, *Clinical Review*, FDA, 201, 212 (Apr. 22, 2016). The SAE Chart below is also attached as Exhibit C hereto:

SERIOUS ADVERSE EVENT CHART						
Patient Number	SAE Number * Serious Liver Injury ("SLI") *	Date Dosed	Date ICPT Received AE Report	Case Number	Stage of PBC	Correct or Incorrect Dose
1	**SLI 1**	06/17/2016	06/24/2016	12773288	Early	Correct
2	**SLI 2**	08/02/2016	09/01/2016	12754902	Early	Correct
3	**SLI 3**	Unknown	10/06/2016	12870725	Early	Correct
4	**Death 1**	Unknown	10/20/2016	12904567	Unknown	Unknown
5	**Death 2**	08/2016	10/20/2016	13097723	Late	Incorrect
6	**Death 3**	09/08/2016	11/10/2016	12965126	No PBC	Unapproved Indication
7	**Death 4**	08/26/2016	12/27/2016	13086204	Late	Incorrect
8	**SLI 4**	10/2016	01/04/2017	13128473	Late	Incorrect
9	**Death 5**	Unknown	01/11/2017	13145646	Unknown	Unknown
10	**Death 6**	12/30/2016	01/30/2017	13193696	Unknown	Unknown
11	**Death 7**	11/30/2016	02/01/2017	13159955	Unknown	Unknown
12	**SLI 5**	11/03/2016	03/07/2017	13372258	Late	Incorrect
13	**SLI 6**	Unknown	03/10/2017	13367794	Early	Unknown
14	**Death 8**	08/04/2016	03/16/2017	13347042	Unknown	Unknown
15	**Death 9 & SLI 7**	12/09/2016	04/06/2017	13356448	Late	Incorrect
16	**Death 10**	11/2016	04/07/2017	13374253	Late	Correct
17	**Death 11**	02/18/2017	04/10/2017	13424267	Late	Incorrect
18	**SLI 8**	03/2017	04/13/2017	13487750	Early	Correct
19	**Death 12**	11/11/2016	04/20/2017	13372203	Unknown	Unknown
20	**Death 13**	04/2017	05/03/2017	13500516	Late	Incorrect
21	**Death 14**	10/10/2016	05/11/2017	13651412	Late	Incorrect
22	**Death 15**	02/23/2017	06/09/2017	13515063	Unknown	Unknown
23	**SLI 9**	02/2017	06/12/2017	13351280	Late	Incorrect
24	**Death 16 & SLI 10**	03/2017	06/14/2017	13579422	Late	Incorrect
25	**Death 17**	02/2017	06/20/2017	13374189	Late	Incorrect
26	**Death 18 & SLI 11**	Pre 01/2017	06/27/2017	13518654	Late	Incorrect
27	**Death 19**	Unknown	06/30/2017	13703394	Unknown	Unknown

87. Beginning on June 24, 2016, a week before Intercept launched its public offering for approximately $447.7 million in convertible notes (*see* Intercept Pharmaceuticals, Inc., Current Report, Form 8-K (Ex. 99.1) (July 7, 2016)), the first case of serious liver injury that later became the subject of the FDA's Safety Announcement was reported to Intercept. *See* SAE Chart, Patient Number 1. Within just four days of starting on Ocaliva, this patient experienced dramatically increased bilirubin and ALP levels. *Id.* Over the Class Period, at least 10 other patients experienced similar liver damage, for a total of ***11 patients***. *See* SAE Chart, Patient Numbers 1, 2, 3, 8, 12, 13, 15, 18, 23, 24, and 26. Five of these patients had early-stage PBC and thus had only mild hepatic impairment when they experienced the adverse event. *See* SAE Chart, Patient Numbers 1, 2, 3, 13, and 18.

88. On October 20, 2016, the safety reports became fatefully worse when Intercept observed the first death associated with Ocaliva use. *See* SAE Chart. Patient Number 4. From October 20, 2016 to June 31, 2017, a mere 8 months, an additional 18 deaths were linked Ocaliva use, for a total of ***19 deaths***. *See* SAE Chart, Patient Numbers 4, 5, 6, 7, 9, 10, 11, 14, 15, 16, 17, 19, 20, 21, 22, 24, 25, 26, and 27.

89. Not surprisingly, many of these serious safety events concerned incorrect, excessive dosing of late-stage PBC patients. In its Safety Announcement, the FDA noted 12 events of misdosing, where a patient with late-stage PBC received the daily dose of Ocaliva, instead of the weekly dose. . *See* SAE Chart, Patient Numbers 5, 7, 8, 12, 15, 17, 20, 21, 23, 24, 25, 26.

90. For example, oometime in August 2016, a patient with decompensated cirrhosis was prescribed and began taking the 5 mg daily dosage of Ocaliva. *See* SAE Chart, Patient Number 5. Because decompensated cirrhosis is a sign of late-stage PBC and, as such, this

patient should have been given the 5 mg weekly dosage of Ocaliva, this dose was seven times higher than the recommended dosage for this patient. Over the Class Period, at least an additional 11 patients, all of whom had late-stage PBC, received this incorrect, grossly excessive dose of Ocaliva, for a total of ***12 misdosed patients***. *See* SAE Chart, Patient Numbers 5, 7, 8, 12, 15, 17, 20, 21, 23, 24, 25, 26. This subset of patients noted by the FDA are likely the tip of the iceberg and confirm that patients with late-stage PBC were being systematically overdosed with Ocaliva.

91. Between June 30, 2017—when the FDA cut off its safety review—and September 21, 2017—when the FDA issued its Safety Announcement—an additional 11 patients would die, raising the total deaths to 30 out of the approximately 3,000 patients who were taking the drug. *See Ocaliva*, FDA Adverse Event Reporting (FAERS), https://fis.fda.gov/sense/app/d10be6bb-494e-4cd2-82e4-0135608ddc13/sheet/45beeb74-30ab-46be-8267-5756582633b4/state/analysis (last visited July 30, 2018).

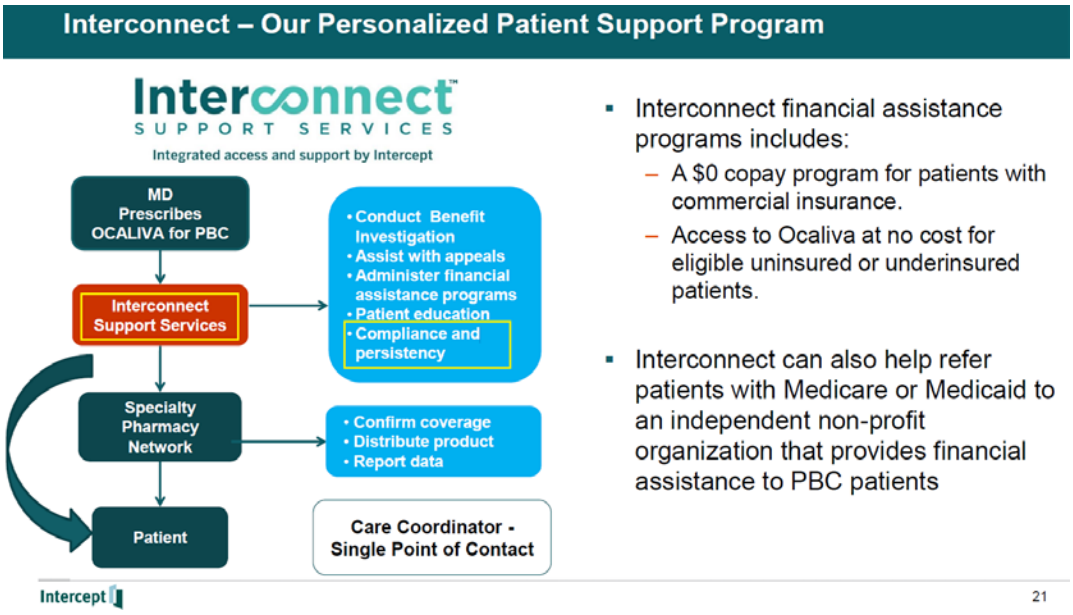
H. Defendants Make False And/Or Misleading Statements Concealing That Patients Were Not Complying With The Dosing Regimen For Ocaliva

92. From the start of the Class Period on June 9, 2016 until the FDA's Safety Announcement on September 21, 2017, Defendants concealed that late-stage PBC patients were being excessively dosed by making false and/or misleading statements regarding patients' compliance with the dosing regimen for Ocaliva and by failing to disclose that the risk of incorrect dosing had already come to fruition. These statements were especially misleading when considered in the context of the FDA's specific instructions to Intercept that late-stage PBC patients should take a lower, weekly dose of Ocaliva because they have more compromised livers, and are thus more vulnerable to drug toxicity (¶41) and the Company's statements

marketing Interconnect as a personalized patient support program that facilitated compliance with the FDA-imposed dosing regimen (¶52).

1. Defendants Make False and/or Misleading Statements Regarding Patients' Compliance With the Ocaliva Dosage Regimen

93. On June 9, 2016, when the Class Period began, the Company published a power point presentation on the Events & Presentations page of its website that stated in relevant part:[8]



Intercept Pharmaceuticals, *Corporate Presentation*, 21 (June 9, 2016).

94. This statement was materially false and/or misleading when made because Intercept failed to disclose that Intercept created and used an Enrollment Form submitted through the Interconnect system that caused late-stage PBC patients to receive the incorrect dose of Ocaliva because the Enrollment Form did not provide an option to prescribe the proper weekly dose of Ocaliva, as set forth in ¶54.

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[8] The yellow boxes were added by counsel to highlight the portions of the statement alleged to be false and/or misleading. Furthermore, the other statements being challenged as false and/or misleading in this complaint are those statements that are ***bolded***, ***italicized***, and in some instances, ***underlined*** for emphasis.

95. The Company presented this exact slide again on November 3, 2016, January 12, 2017, February 23, 2017, May 4, 2017, June 6, 2017, and July 31, 2017. The statements in the slides presented on those dates were materially false and/or misleading when made because Intercept failed to disclose that:

- Intercept created and used an Enrollment Form submitted through the Interconnect system that caused late-stage PBC patients to receive the incorrect dose of Ocaliva because the Enrollment Form did not provide an option to prescribe the proper weekly dose of Ocaliva, as set forth in ¶54;
- As of the dates of each of these statements, patients with late-stage PBC had been misdosed, as set forth in the SAE Chart.

96. On September 13, 2016, during the Morgan Stanley Global Healthcare Conference (transcript available through Bloomerberg), McMinn and Pruzanski stated in relevant part:

> McMinn: In terms of the plan or in terms of the population, other metrics to consider, ***we've got basically everybody starting on the 5 milligram dose***, which is really important for future persistency, which I am sure you have a question on that. But it's again a little bit early to really talk about persistency, ***but getting patients on the right starting dose is obviously a long ways towards getting to where we want to be there***. . . .
>
> Pruzanski: ***Yeah. So you mentioned Interconnect, this is our patient services hub that does everything from help facilitate getting patients on drug to continue to monitor them, we do have adherence programs***, we're going to be implementing. I think with respect to persistency, again as Rachel just mentioned, it's too early days, but the one issue of course that might be of concern is the one notable side effect that we see with the drug, which is dose-dependent pruritus.

97. This statement was materially false and/or misleading when made because McMinn, Pruzanski, and Intercept failed to disclose that Intercept created and used an Enrollment Form that caused late-stage PBC patients to receive the incorrect dose of Ocaliva

because the Enrollment Form did not provide an option to prescribe the proper weekly dose of Ocaliva, as set forth in ¶54.

98. On February 23, 2017, on the 2016 Fourth Quarter Earnings Conference Call (transcript available through FDWire), the following exchange occurred between Kim and an analyst at Cowen:

> Analyst: Got it. And my follow-up has to do with the launch. Are you finding that the lack of experience with more advanced disease patients is in any way limiting the drug's use, from a safety perspective, in PBC? . . . .
>
> Kim: Yes, so Richard. So great question as far as the more advanced patients. ***So we do see patients with complicated cirrhosis that are being treated with Ocaliva, but we're not really seeing major differences as far as the treatment approach to these patients. Obviously, on our label, if patients have very advance disease and hepatic impairment, there are more limitations as far as starting with your dosing***. But in general, it's a relatively small patient population. ***It's not one that we've seen a huge impact to, and I would say generally, people are becoming better experienced in how to manage these patients in the marketplace, as well.***
>
> Analyst: And there's been no safety pushback or any concerns that you've heard of?
>
> Kim: I'd say generally, not more. I mean, we do obviously have reports that are reported in, but generally, we're not hearing a lot more issues out there. ***I think it's been well communicated on how to properly manage those patients. It's well documented within our label, so we're very careful to make sure people understand how to actually start, initiate, and manage patients with hepatic impairment.***

99. This statement was materially false and/or misleading when made because Kim and Intercept failed to disclose that:

- Intercept created and used an Enrollment Form that caused late-stage PBC patients to receive the incorrect dose of Ocaliva, because the Enrollment Form did not provide an option to prescribe the proper weekly dose of Ocaliva, as set forth in ¶54; and

- By February 23, 2017, at least ***3 patients*** with late-stage PBC had been misdosed, as set forth in the SAE Chart.

100. On May 17, 2017, at the Bank of America Merrill Lynch Health Care Conference (transcript available through FDWire), the following exchange occurred between an analyst and CEO Pruzanski:

> Analyst: And also, in terms of the experiences you have, experiences so far, can you maybe talk a little bit about the persistence or compliance rate for the patients who have been prescribed with Ocaliva?
>
> Pruzanski: Well -- and, ***of course, compliance persistency are key here***. ***This is a lifetime therapy, and so our goal is not only to get patients who are eligible for therapy on to Ocaliva but to keep them there***. ***We've spent a lot of time and investment in building a patient services hub called Interconnect***. The majority of scripts come in through Interconnect, and that gives us a really nice line of sight directly to patients so that we can help them and physicians' offices navigate the (inaudible) with payers, with insurance companies, get them onto treatment, answer their questions and then, just as importantly, retain those patients, right, so if any issues come up, reminders for refills, et cetera, et cetera. So we're spending a lot of time and effort on that. As we've said, this early in the launch, it's too early to make definitive comments about persistency and compliance other than, anecdotally, ***we're happy with where we are***. ***There've been no surprises.*** The patients seem to have received the drug very well, the patient community. And of course, as I mentioned, physicians are very enthusiastic about the availability of Ocaliva.

101. This statement was materially false and/or misleading when made because Pruzanski and Intercept failed to disclose, that:

- Intercept created and used an Enrollment Form that caused late-stage PBC patients to receive the incorrect dose of Ocaliva because the Enrollment Form did not provide an option to prescribe the proper weekly dose of Ocaliva, as set forth in ¶54; and
- By May 17, 2017, at least ***8 patients*** with late-stage PBC had been misdosed, as set forth in the SAE Chart.

102. On July 31, 2017 during Intercept's Second Quarter 2017 Earnings Conference Call (transcript available through Bloomerberg), Kim stated:

> ***We are encouraged by the persistency and compliance with Ocaliva thus far***, which is tracking in line or slightly better than our UDCA benchmark. . . . Finally, ***our compliance and persistency initiatives have been enhanced. Through our patient services hub, Interconnect, and the specialty pharmacies***, we have increased the frequency of patient outreach with customized communications based on each patient profile. There are also more directed communications and resources to the physician offices to have a more team approach to patient management.

103. This statement was materially false and/or misleading when made because Kim and Intercept failed to disclose that:

- Intercept created and used an Enrollment Form that caused late-stage PBC patients to receive the incorrect dose of Ocaliva because the Enrollment Form did not provide an option to prescribe the proper weekly dose of Ocaliva, as set forth in ¶54; and
- By July 31, 2017, at least ***12 patients*** with late-stage PBC had been misdosed, as set forth in the SAE Chart.

104. On August 16, 2017, at the Wedbush PacGrow Healthcare Conference (transcript available through Bloomberg) Pruzanski explained that:

> ***[W]e set-up a patient services hub called Interconnect, which I think has done a great job in handholding patients and physicians' offices from the time of scripts to getting patients on drug and beyond***. And I'm very pleased to say that we're now at from writing script to converting patients to drug at around three week [sic], which is very much in keeping with sort of best in class practice.
>
> And then the third area where Interconnect of course plays a major role is ensuring that once patients get on drug that they stay on drug if they're able to – if they're tolerating the drug. And so, ***adherence programs are major area of focus***. ***And what we announced in Q2, we now have some visibility on compliance and persistency. And I'm very pleased to say that in the real world, our drug is performing at least as well if not better than the standard-of-care generic product***

> ***URSO***, which is generally considered very well tolerated and has been around for a generation as I mentioned.

105. This statement was materially false and/or misleading when made because Pruzanksi and Intercept failed to disclose that:

- Intercept created and used an Enrollment Form that caused late-stage PBC patients to receive the incorrect dose of Ocaliva because the Enrollment Form did not provide an option to prescribe the proper weekly dose of Ocaliva, as set forth in ¶54; and
- By August 16, 2017, at least ***12 patients*** with late-stage PBC had been misdosed, as set forth in the SAE Chart.

106. On a September 6, 2017 conference call with an analyst at Robert W. Baird & Co., Inc. (transcript available through Bloomberg), the following discussion occurred:

> Analyst: So what's steps are you guys taken to kind of increase awareness for both patients and physicians of PBC?
>
> Intercept Officer: Okay, I mean, something is clearly—we've done several things, I think, we've also talked about how the awareness has gone up amongst, during the last quarter, amongst unaided awareness, amongst physicians. And a lot of it is really driven through our targeting efforts . . . we're also ***very much focused on is compliance and persistency***, right, because this is something that over time is important. And for that ***we have our patient services hub, and we also have a specialty pharmacy by which we distributed. So we have whole host of programs that help educate not only physicians, but also patients that sign up as part of the hub in terms of how to take the medi[c]ation and so forth***, so.

107. This statement was materially false and/or misleading when made because Intercept failed to disclose that:

- Intercept created and used an Enrollment Form that caused late-stage PBC patients to receive the incorrect dose of Ocaliva because the Enrollment Form did

not provide an option to prescribe the proper weekly dose of Ocaliva, as set forth in ¶54; and

- By September 6, 2017, at least ***12 patients*** with late-stage PBC had been misdosed, as set forth in the SAE Chart.

2. Defendants Fail To Disclose that the Risk of Incorrect Dosing Had Already Come to Fruition

108. In the risk factors section of all of Intercept's quarterly and annual financial reports filed with the SEC during the Class Period, Defendants warned that Ocaliva ***could*** have adverse side effects if "misused" without disclosing that the drug was already being misused and patients were experiencing Potential Side Effects from its misuse. This risk factor stated:

> ***[T]he use of Ocaliva in a non-trial setting may result in the occurrence of*** unexpected or a greater incidence of side effects, adverse reactions or ***misuse that may negatively affect the commercial prospects of Ocaliva.***

109. This risk factor was misleading when made in Intercept's quarterly financial report for the second quarter of 2016, filed on August 9, 2016 and signed by Pruzanski and Kapadia, because Pruzanski, Kapadia, and Intercept failed to disclose, that:

- Intercept created and used an Enrollment Form that caused patients to misuse Ocaliva because the Enrollment Form did not provide an option to prescribe a weekly dose of Ocaliva to patients with late stage PBC, as set forth in ¶54; and
- Patients had misused Ocaliva because ***at least 1 patient with late stage PBC had incorrectly received the daily dose of Ocaliva***, as set forth in the SAE Chart.

110. This risk factor was misleading when made in Intercept's quarterly financial report for the third quarter of 2016, filed on November 9, 2016 and signed by Pruzanski and Kapadia, for the same reasons set forth in ¶108, and by that time, ***at least 4 patients with late***

stage PBC had incorrectly received the daily dose of Ocaliva, ***one of whom died***, as set forth in the SAE Chart.

111. This risk factor was misleading when made in Intercept's annual financial report for 2016, filed on March 1, 2017 and signed by Pruzanski and Kapadia, for the same reasons set forth in ¶108, and by that time, ***at least 10 patients with late stage PBC had incorrectly received the daily dose of Ocaliva***, ***2 of whom died and 1 of whom experienced serious liver injury***, as set forth in the SAE Chart.

112. This risk factor was misleading when made in Intercept's quarterly financial report for the first quarter of 2017, filed on May 10, 2017 and signed by Pruzanski and Kapadia, for the same reasons set forth in ¶108, and by that time, ***at least 12 patients with late stage PBC had incorrectly received the daily dose of Ocaliva***, ***4 of whom died, 1 of whom suffered serious liver injury and then died, and 2 of whom suffered serious liver injury***, as set forth in the SAE Chart.

113. This risk factor was misleading when made in Intercept's quarterly financial report for the first quarter of 2017, filed on August 3, 2017 and signed by Pruzanski and Kapadia, for the same reasons set forth in ¶108, and by that time, ***at least 12 patients with late stage PBC had incorrectly received the daily dose of Ocaliva***, ***all of whom either died or suffered serious liver injury***, as set forth in the SAE Chart.

114. At no point during the Class Period did Defendants update the aforementioned risk factors to warn that patients had misused Ocaliva, as required by 17 C.F.R. § 229.305(c).

I. Defendants Make False And/or Misleading Statements Concealing That Patients Were Not Tolerating Ocaliva

115. During the Class Period, Defendants concealed the occurrence of Potential Side Effects by making false and/or misleading statements regarding patients' tolerance of Ocaliva.

These statements were especially misleading when considered in the context of the FDA's historical concern over liver injury (¶¶36-38), the FDA's concern over Ocaliva's potential to cause liver injury (¶¶41-49), and the 2 deaths in PBC patients out of the 1,325 patients treated in all of the Ocaliva clinical trials (¶40).

1. Defendants Make False and/or Misleading Statements Regarding Patients' Tolerance of Ocaliva

116. At the Morgan Stanley Healthcare Conference held on September 13, 2016 (transcript available through Bloomberg), the following exchange occurred between Pruzanski and an analyst:

> Analyst: What's been the feedback from the prescribers so far for the patients they've started on the drug?
>
> Pruzanski: ***Feedback has been positive***.

117. This statement was materially false and/or misleading when made because Pruzanski and Intercept failed to disclose that the Company had received significant negative feedback as Ocaliva had been linked to ***2 cases of serious liver injury***. *See* SAE Chart.

118. During that same conference, the following interaction occurred after an analyst asked about whether Intercept had any guidance about its expectation for the number of lives covered by the next year:

> McMinn: And I will just maybe interject and provide a little bit more color. So, overall ***I think the headlines that we're trying to mention now is, no big surprises***, right. So there's always a tweaks, things that you do for a launch. ***But nothing that's kind of coming sideways***. So it was counter to our expectations for launch either. . . .
>
> Pruzanski: Yeah. So you mentioned Interconnect, this is our patient services hub that does everything from help facilitate getting patients on drug to continue to monitor them, we do have adherence programs, we're going to be implementing. I think with respect to persistency, again as Rachel just mentioned, it's too early days, ***but the one issue of course that might be of concern is the one notable side effect that we see with the drug, which is dose-dependent pruritus.***

> The first key point is that the vast majority of patients are being started appropriately at the 5 milligram daily doses Andy, from the Phase 3 patients who started at 5 milligram and then titrated over time to 10 milligram, had a much better tolerability profile. ***We only had one patient dropped out of the Phase 3 due to pruritus and would hope to see the same real world experience on the drug.*** Again, we'll know more about persistency once patients are titrated up to the 10 and have more longevity on treatment.

119. This statement was materially false and/or misleading when made because McMinn, Pruzanski, and Intercept failed to disclose that:

- There had been "big surprises" and things had "come in sideways" during the launch because Ocaliva had been linked to ***2 cases of serious liver injury***, *see* SAE Chart; and
- ***2 cases of serious liver injury*** had been linked to Ocaliva (see SAE Chart), which is material because the Potential Side Effects of Ocaliva were more severe than Defendants led investors to believe.

120. At the J.P. Morgan Healthcare Conference held on January 11, 2017 (transcript available through Bloomberg), Pruzanski stated:

> [A]s recommended in the label, the vast majority of patients are being initiated at 5 milligrams once a day. And this dose was significantly better tolerated in the Phase 3 than the starting patients at 10 milligrams apropos the pruritus that I mentioned before. So far, anecdotally, while it's still early days, we have come to understand that ***in the real world, the real world experience of patients has been largely very positive***.

121. This statement was materially false and/or misleading when made because Pruzanski and Intercept failed to disclose that by this date the experience of patients had not been "largely positive" and Ocaliva had been linked to ***5 deaths and 4 cases of serious liver injury***. *See* SAE Chart.

122. On February 23, 2017, on Intercept's Fourth Quarter 2016 Earnings Conference Call (transcript available on FDWire), the following discussion occurred between Kim and an analyst:

> Analyst: Are you finding that the lack of experience with more advanced disease patients is in any way limiting the drug's use, from a safety perspective, in PBC? And linked to that, could there be any informational crosstalk between the advanced disease population in COBALT and the Phase 3 NASH fibrosis study that you plan on starting later this year? Like, would one inform the other in any way?
>
> Kim: Yes, so Richard. So great question as far as the more advanced patients. So we do see patients with complicated cirrhosis that are being treated with Ocaliva, but we're not really seeing major differences as far as the treatment approach to these patients. Obviously, on our label, if patients have very advance disease and hepatic impairment, there are more limitations as far as starting with your dosing. But in general, it's a relatively small patient population. It's not one that we've seen a huge impact to, and I would say generally, people are becoming better experienced in how to manage these patients in the marketplace, as well.
>
> Analyst: And there's been no safety pushback or nay concerns that you've heard of?
>
> Kim: ***I'd say generally, not more. I mean, we do obviously have reports that are reported in, but generally, we're not hearing a lot more issues out there***. I think it's been well communicated on how to properly manage those patients. It's well documented within our label, so we're very careful to make sure people understand how to actually start, initiate, and manage patients with hepatic impairment.

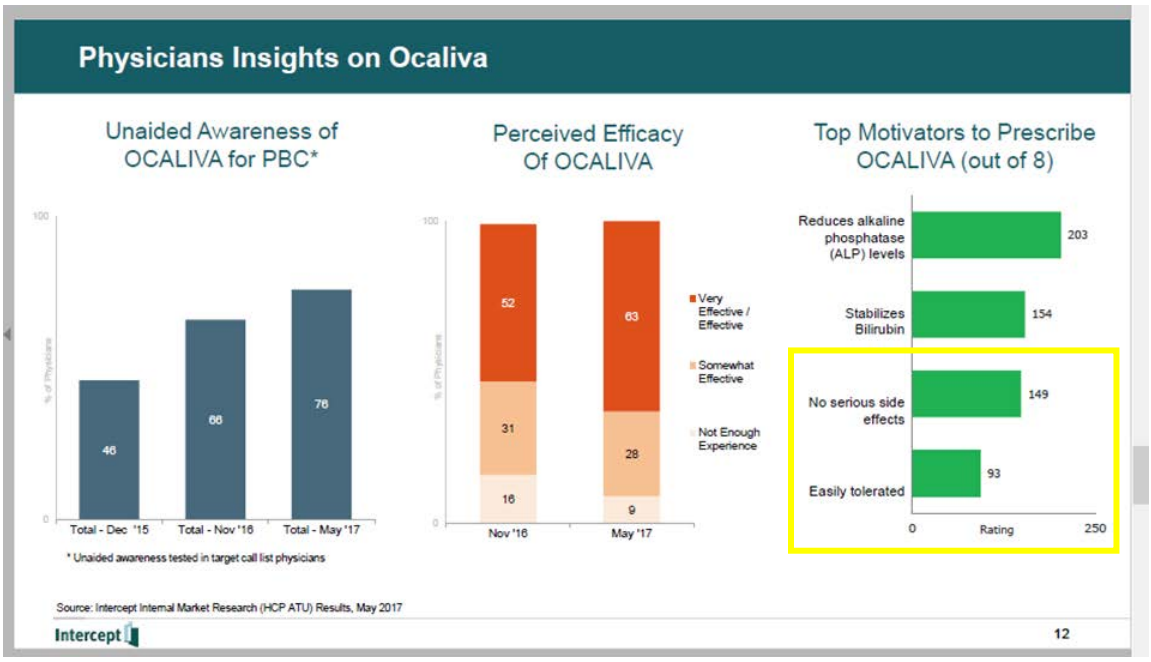
123. This statement was materially false and/or misleading when made because Kim and Intercept failed to disclose that by this date the Company had heard of significant issues regarding safety as Ocaliva had been linked to ***7 deaths and 4 cases of serious liver injury***, and of these cases, ***at least 2 of these deaths and 1 of these cases of serious liver injury were in late-stage PBC patients***. *See* SAE Chart.

124. On May 4, 2017, on Intercept's First Quarter 2017 Earnings Conference Call (transcript available through FDWire), the following discussion occurred between an analyst and Kim:

> Analyst: I'm just curious about, with the doctors that are treating Ocaliva, do you think that it's a matter of just time for them to putting more patients on or is it experience with the drug and maybe characterize how discontinuation stands versus your expectations?
>
> Kim: . . . Yes, as far as the question as far as the physicians treating with Ocaliva, yes, I'd say it's a bit of a mixed bag. Obviously, we have physicians who have gained a lot of experience who have treated a lot of patients, but we still have a broad treater base that we have to continue to build. So I think we're in a pretty good spot. ***In general, when people have prescribed with Ocaliva, feedback has been quite positive.*** But there's a lot more physicians that we still have to reach.

125. This statement was materially false and/or misleading when made because Kim and Intercept failed to disclose that by this date the Company had received significant negative feedback as Ocaliva had been linked to ***13 deaths and 8 cases of serious liver injury***. *See* SAE Chart.

126. On July 31, 2017, during Intercept's Second Quarter 2017 Earnings Conference Call, the Company displayed a power-point presentation that stated, in a survey of doctors that had prescribed Ocaliva, ***149 doctors were motivated to prescribe Ocaliva because it had*** "***no serious side effects***" and ***93 were motivated to prescribe it because it was*** "***easily tolerated***." See the portion of the slide below that counsel has highlighted with a yellow outline:



Intercept Pharmaceuticals, Inc., *Second Quarter 2017 Earnings Presentation*, 12 (Jul. 31, 201).

127. This statement was materially false and/or misleading when made because Intercept failed to disclose that by this date doctors had reported to Intercept ***19 deaths and 11 cases of serious liver injury*** that had been linked to Ocaliva and were Potential Side Effects. *See* SAE Chart.

128. During the same presentation cited in ¶127 above, Kim echoed the following sentiment:

> The perceived efficacy of Ocaliva from physicians has grown from 52% at the end of last year up to 63%. ***Top motivation to prescribe are based on strong beliefs on efficacy and no serious side effects***. . . .
>
> ***
>
> We are encouraged by the persistency and compliance with Ocaliva thus far . . . ***We feel that the tolerability profile is very well understood and is seen overall as good and manageable. We're excited about the continued response about Ocaliva that we receive from physicians and patients***.

129. This statement was materially false and/or misleading when made because Kim and Intercept failed to disclose that by this date doctors had reported to Intercept ***19 deaths and 11 cases of serious liver injury*** that had been linked to Ocaliva and were Potential Side Effects. *See* SAE Chart.

2. Defendants Make Materially False and/or Misleading Statements to Analysts Regarding Patients' Tolerance of Ocaliva

130. In addition to making materially false and/or misleading statements directly to the market, throughout the Class Period, Defendants repeatedly made materially false and/or misleading statements to analysts that Defendants knew would be relayed to the market.

131. During the Class Period, Intercept was a highly covered company that attracted the attention of at least 14 large financial institutions with investment research arms.[9] The research analysts at these institutions were in frequent communication with executives at Intercept and would often disclose these communications in reports throughout the Class Period.

132. For example, on December 5, 2016, Leerink issued an analyst report entitled "EU Approval of Ocaliva in PBC Will Drive Further Uptake in 2017" and on December 14, 2016 issued another report entitled "Meeting with Mgmt Highlights Solid PBC Launch, Competitive NASH Environment" both of which stated in relevant part:

> In our recent meeting with management, ICPT expressed bullishness about the market opportunity for Ocaliva in the US, noting that demand in the company's Interconnect hub has been solid and they have noticed greater than expected pull through for prescriptions through this channel. ***ICPT is not hearing any negative concerns on the tolerability of OCA. Around 95% of patients are starting on the 5mg dose which is very well tolerated.***

133. This statement was materially false and/or misleading when made because Intercept failed to disclose that by this date, patients taking Ocaliva were subject to Potential Side Effects as evidenced by the fact Ocaliva had been linked to ***4 deaths and 3 cases of liver injury***. *See* SAE Chart.

134. On February 23, 2017, RBC published an analyst report entitled "Takeaways from HC Conference: Ocaliva Sales Are Moving Up, NASH Getting More De-Risked" noting that they had recently hosted CEO Pruzanski and CBO/CSO McMinn at a conference and that,

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[9] These financial institutions included BMO Capital Markets ("**BMO**"), Cantor Fitzgerald and Company, Cowen and Company, LLC, ("**Cowen**") Credit Suisse Group AG, Jefferies Financial Group, Inc., JMP Securities, LLC, Laidlaw & Company (UK) Ltd., Leerink Partners, LLC, ("**Leerink**"), Morgan Stanley & Co., LLC, ("**Morgan Stanley**") Oppenheimer and Company, Inc., RBC Capital Markets, LLC, ("**RBC**"), UBS Securities, LLC, ("**UBS**"), Wedbush Securities, Inc., ("**Wedbush**"), and Wells Fargo Securities, LLC.

"Management suggested ongoing early but positive persistency rates similar to clinical trials, and ***side effects like pruritus are manageable with dose titration.***"

135. This statement was materially false and/or misleading when made because Pruzanski, McMinn, and Intercept failed to disclose that:

- Patients taking Ocaliva were subject to Potential Side Effects as evidenced by the fact Ocaliva had been linked to ***7 deaths and 4 cases of serious liver injury***, *see* SAE Chart; and
- ***7 deaths and 4 cases of serious liver injury*** had been linked to Ocaliva (*see* SAE Chart), which is material because the Potential Side Effects of Ocaliva were more severe than Defendants led investors to believe.

136. On June 12, 2017, Cowen published an analyst report entitled "Key Takeaways From Group Lunch With Mgmt" noting that at a recent group investor lunch with Intercept management "ICPT indicated that":

> [T]he Ocaliva launch continues to progress well, supported by the IMS Rx trend observed. Mgmt indicated that time to fill through InterConnect remains at ~3wks, which we believe represents a mature, well executed orphan drug launch. ***The company also reiterated that no problematic trends in tolerability, specifically around treatment-related pruritus,*** and discontinuations/persistence ***have yet been reported***. Interestingly, 50% of Ocaliva patients have not uptitrated from the 5mg dose to the 10mg dose, which could be related to the excellent persistence to date.

137. This statement was materially false and/or misleading when made because Intercept failed to disclose that:

- Patients taking Ocaliva were subject to Potential Side Effects as evidenced by the fact Ocaliva had been linked to ***15 deaths and 9 cases of serious liver injury***, *see* SAE Chart; and

- ***15 deaths and 9 cases of serious liver injury*** had been linked to Ocaliva (*see* SAE Chart), which is material because the Potential Side Effects of Ocaliva were more severe than Defendants led investors to believe.

J. The FDA Reviews 13-Month Ocaliva Safety Data

138. On July 31, 2017, the Company told the market that a single patient died due to acute renal and liver failure in its Phase II CONTROL trial, which was testing Ocaliva as a treatment for NASH. *See* Press Release: Intercept Pharmaceuticals, Inc., "CONTROL Trial Shows Statin Therapy Reversed LDL Increases to Below Baseline Levels in NASH Patients Treated with OCA," (Form 8-K) (Ex. 99.2) (Jul. 31, 2017). On the 2017 Second Quarter Earnings Call on the same date, Pruzanski clarified, "this is a really unfortunate case of an individual who is quite sick and had a lot of clinical complications in the course of his disease. And exercising an abundance of caution given the death, we decided that we couldn't rule out that it was possibly related."

139. The market was concerned by this single death of a patient on Ocaliva. For example, a Morgan Stanley analyst released a report the following day entitled "Solid Ocaliva Quarter Overshadowed by CONTROL Data Implications for larger NASH Population" in which he noted that this one death, *inter alia*, "raised concerns about whether Ocaliva will remain a viable drug for NASH, especially in the face of advancing competition[.]"

140. According to CW1, as a result of ***this single death***, in August 2017, the FDA conducted a 13-month review of the safety database for Ocaliva. *See* FDA Safety Announcement. Based on this review, which included consideration of the 19 deaths and 11 cases of serious liver injury (*see* SAE Chart), the FDA reassessed Ocaliva's safety profile. *See id.* The FDA was also concerned over the frequency that patients received the incorrect dose of Ocaliva, specifically the 12 patients with late stage PBC who were improperly given the higher

dose of the drug. *See id.*

K. The Truth Is Revealed

1. The Truth is Partially Revealed

141. Finally, Intercept could no longer hide the deadly truth. When the market opened on September 12, 2017, the Company posted a ***"Dear Healthcare Provider" Letter*** warning about the danger of late stage PBC patients receiving an excessive dose of Ocaliva. Press Release: Intercept Pharmaceuticals, Inc., *Intercept* Statement *Regarding Ocaliva® (obeticholic acid) Safety and Dosing in Primary Biliary Cholangitis (PBC) Patients* (Sept. 25, 2017). The letter stated in relevant part:

> Liver injury, liver decompensation, liver failure, and death have been reported in patients with moderate to severe hepatic impairment when OCALIVA was dosed more frequently than recommended in labeling for such patients. In addition, serious liver adverse events have been reported in patients initiating therapy without cirrhosis or with mild liver impairment. Liver-related adverse events have occurred both early in treatment and after months of treatment. . . .
>
> Considering the risk for liver injury associated with incorrect dosing of patients with advanced stage PBC, it is important for prescribers to:
>
> - identify patients with impaired hepatic function at the start of OCALIVA treatment and ensure these patients are prescribed the recommended approved starting dosage regimen (i.e., 5 mg once weekly).
>
> - monitor patients during treatment with OCALIVA for progression of their PBC disease and reduce the dosing frequency to once weekly for patients who progress to moderate hepatic impairment (Child-Pugh Class B).

142. The market was shocked, as Defendants had never given any indication that patients were dying, experiencing liver injury, or receiving the wrong dose of Ocaliva. Thus, Intercept's common stock fell $22.73 per share from a close of $113.48 per share on September 11, 2017 to a close of $90.75 per share on September 13, 2017, a drop of approximately 20%.

143. To mitigate any further damage from this announcement, Intercept's management team embarked on a whirlwind press tour during which they misled the market regarding the severity of the problems linked to Ocaliva.

144. At the Morgan Stanley Healthcare Conference on September 12, 2017 (transcript available through FD Wire), Defendants downplayed the significance of the Dear Health Care Provider Letter, explaining:

> Pruzanski: But again, use appropriately, there is clearly an appropriate therapeutic index here. And just, I made this point a little earlier, ***what we're talking about here that is referred to in the Dear Doctor letter and the Dear Healthcare Provider letter refers to the 2% to 3%, the tiny proportion of this population who have the most advanced disease*** and in fact – I mean, that's the prevalence out there, but it also matches up with our commercial experience in this population.
>
> ***
>
> McMinn: PBC, it's different. It's 5 going to 10 and 10 did augment efficacy slightly. NASH, as Mark mentioned, we're evaluating 10; we're evaluating 25. So every liver disease, we think, needs to have its own set of clinical data to figure out what's the most appropriate dose. ***And as you get into these very, very advanced cirrhotics, you're going to have to back off on the dose. I think that's really the main takeaway message from today's news***.

145. This statement was materially false and/or misleading when made because Pruzanski, McMinn, and Intercpet failed to disclose that the Dear Healthcare Provider Letter did not only result from late-stage PBC patients receiving the incorrect daily dose of Ocaliva, because in the adverse events reviewed by the FDA, at least 1 patient died and 4 patients experienced serious liver injury, ***even when they took the correct dosage of Ocaliva***. *See* SAE Chart.

146. On September 12, 2017, an analyst report published by UBS entitled "Our Takeaways on the 'Dear Health Care Provider' Letter" relayed statements made by Intercept Management during a lunch with the analysts, stating:

> This morning, Intercept posted a "Dear Health Care Provider" letter to remind providers of dosing recommendations when treating patients with moderate to severe hepatic impairment. We had a chance to speak with management, who indicated that ***the patients in question had received daily dosing instead of the recommended weekly dosing for this patient population***. . . .
>
> Key Takeaways:
>
> ***[1] There were a relatively small number of postmarketing cases, on the order of ~ 10. [2] Management reported that no cases were deemed to be caused by Ocaliva. [3] Instead of weekly dosing, these patients were treated with daily dosing (e.g. instead of 5mg QW [every week], they received 5mg QD [every day])***. [4] The company had already been in discussions with the FDA to determine how to increase monitoring frequency in its clinical trials, but this was not about dosing or safety.

147. This statement was materially false and/or misleading when made because Intercept failed to disclose that:

- The Dear Healthcare Provider Letter did not only result from late-stage PBC patients receiving the incorrect daily dose of Ocaliva, because in the adverse events reviewed by the FDA, at least 1 patient died and 4 patients experienced serious liver injury, ***even when they took the correct dose of Ocaliva***, *see* SAE Chart;
- The Company's comments on the adverse event reports that were the subject of the Dear Healthcare Provider Letter did not affirmatively rule out the possibility that the events were caused by Ocaliva, as they instead noted that "Although a temporal association exists, it is not sufficient to establish, ***or rule out***, a causal relationship between Ocaliva and the events reported in this case."; and
- The Dear Healthcare Provider Letter was based upon far more than 10 cases of Potential Side Effects, because Ocaliva had been linked to ***19 deaths and 11 cases of serious liver injury, which is triple*** the number provided by Defendants. *See* SAE Chart.

148. On September 18, 2017, an analyst report published by BMO entitled "Key Takeaways From Investor Meeting With Intercept" relayed statements Pruzanski and Kapadia made at a client lunch:

> We hosted a client lunch with CEO Mark Pruzanski and CFO Sandip Kapadia. Discussion focused on the recent "Dear HCP letter" and clarifying misconceptions about AEs seen to date with Ocaliva in the real-world setting, and why read-through to PBC overall and the larger NASH market should be limited. . . .
>
> **Key Points**
>
> **Investor focus remains on the "Dear Healthcare Provider Letter" reported (September 12, 2017)**. ***Management reiterated lack of adherence to the label and known risk in end-stage liver disease (Child-Pugh B and C) as the cause of the observed AEs and deaths in ~10 patients, given Ocaliva exposure is significantly increased in these patients***. Recall end-stage liver disease patients were excluded from the Phase 3 POISE trial in PBC but included in the label with the required dose-adjustment following discussion with the FDA. ***Management noted that no causality was established with patient deaths and Ocaliva given advanced stage of patients***.
>
> **No label changes anticipated**. ***Management continues to expect no label changes will be required and no black box warning will be needed/added***. Thus, any lingering impact of the letter should be limited to effectiveness of physician education efforts (US and ex-US). ***Plus, the population referenced in the Dear HCP Letter represents 2-3% of addressable PBC patients***, so while it is a concerning headline and an education issue that needs addressing, it has limited read-through to the 97-98% of patients eligible for Ocaliva[.]

149. This statement was materially false and/or misleading when made because Kapadia, Pruzanski, and Intercept failed to disclose that:

- The Dear Healthcare Provider Letter did not only result from late-stage PBC patients receiving the incorrect daily dose of Ocaliva, because in the adverse events reviewed by the FDA, at least 1 patient died and 4 patients experienced serious liver injury, ***even when they took the correct dose of Ocaliva***, *see* SAE Chart;

- The Company's comments on the adverse event reports that were the subject of the Dear Healthcare Provider Letter did not affirmatively rule out the possibility that the event was caused by Ocaliva, as they instead noted that "Although a temporal association exists, it is not sufficient to establish, *or rule out*, a causal relationship between Ocaliva and the events reported in this case."; and
- The Dear Healthcare Provider Letter was based upon far more than 10 cases of Potential Side Effects, because Ocaliva had been linked to ***19 deaths and 11 cases of serious liver injury, which is triple*** the number provided by Defendants. *See* SAE Chart.

2. The Truth Is Further Revealed

150. On September 21, 2017, the FDA issued a Safety Alert (attached as Ex. E hereto) entitled, "Ocaliva (obeticholic acid): Drug Safety Communication–Increased Risk of Serious Liver Injury" and also issued a Safety Announcement (attached as Ex. F hereto) entitled "Drug Safety Communication: FDA warns about serious liver injury with Ocaliva (obeticholic acid) for rare chronic liver disease." The Safety Alert was essentially a press release that summarized the Safety Announcement, both of which warned doctors about reports of multiple deaths linked to Ocaliva. The Safety Announcement stated in relevant part:

> The Food and Drug Administration (FDA) is warning that the liver disease medicine Ocaliva is being incorrectly dosed in some patients with moderate to severe decreases in liver function, resulting in an increased risk of serious liver injury and death. These patients are receiving excessive dosing, particularly a higher frequency of dosing than is recommended in the drug label for them. ***Ocaliva may also be associated with liver injury in some patients with mild disease who are receiving the correct dose***. . . .
>
> ***
>
> ***In the 13 months after Ocaliva was approved in May 2016, FDA received reports of serious liver injury or death associated with Ocaliva. The FDA's Adverse***

Event Reporting System (FAERS) includes only reports submitted to FDA, so there may be additional cases about which we are unaware.

Nineteen cases of death were identified, of which eight provided information about the patient's cause of death. The cause of death was reported to be worsening of PBC disease in seven cases, with cardiovascular disease cited in the other case. ***Seven of these eight cases described patients with moderate to severe decreased liver function who received Ocaliva 5 mg daily***, instead of a dose no greater than 10 mg twice weekly as recommended in the label prescribing information for patients with this extent of decreased liver function.

FDA also identified 11 cases of serious liver injury with Ocaliva use. Six of the patients who had moderate or severe decreases in liver function at baseline and developed serious liver injury were receiving Ocaliva 5 mg daily, instead of a dose no greater than 10 mg twice weekly as recommended by FDA in the drug label. Three of these six patients died, which were included in the 19 death cases mentioned previously. Ocaliva was discontinued in four of six cases, which resulted in one patient experiencing symptom resolution and an improvement in a liver blood test. The remaining three cases did not report the response after discontinuation. ***The other five cases of serious liver injury were reported in patients with no or mild decreases in liver function prior to initiating Ocaliva***. Four of these five patients received Ocaliva 5 mg daily, and one did not report the dose. Ocaliva was discontinued in all five cases, which resulted in one patient experiencing symptom resolution and one patient experiencing improved liver blood tests and symptom resolution. The remaining three cases did not report the response after discontinuation.

151. Unlike the Dear Healthcare Provider Letter, this Safety Announcement explicitly disclosed the full extent of the adverse events and the incorrect dosing. Specifically, it noted:

- There were 19 deaths associated with Ocaliva use;
- There were 11 cases of serious liver injury associated with Ocaliva use, 5 of which were seen in patients with early-stage PBC who had mild hepatic impairment.
- There were 12 patients who received the wrong dose of Ocaliva, all of whom had late stage PBC and received a dose exceeding 7 times the recommended dose of Ocaliva.
- There were patients that received the correct dose of Ocaliva that still experienced liver damage.

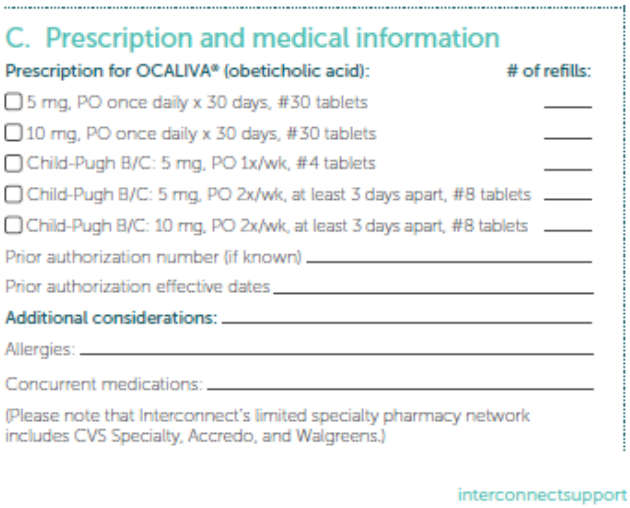
152. What's more, by September 2017, an additional 11 patients had died, bringing the total deaths to 30 patients. *See Ocaliva*, FDA Adverse Event Reporting (FAERS) Public

Dashboard, https://fis.fda.gov/sense/app/d10be6bb-494e-4cd2-82e4-0135608ddc13/sheet/45beeb74-30ab-46be-8267-5756582633b4/state/analysis (last visited July 30, 2018).

153. As a result of the FDA's announcement, Intercept's share price fell $36.53 per share, from a close of $98.12 per share on September 20, 2017 to close at $61.59 per share on September 22, 2017, a two day decline of approximately 37.2%.

L. Relevant Post-Class Period Events

154. Sometime after the Safety Warning, Intercept changed its Enrollment Form to have boxes for doctors to note that s patient was a late-stage PBC patient and would therefore need a weekly dose of Ocaliva. *See* below:



C. Prescription and medical information

Prescription for OCALIVA® (obeticholic acid): # of refills:

- ☐ 5 mg, PO once daily x 30 days, #30 tablets ____
- ☐ 10 mg, PO once daily x 30 days, #30 tablets ____
- ☐ Child-Pugh B/C: 5 mg, PO 1x/wk, #4 tablets ____
- ☐ Child-Pugh B/C: 5 mg, PO 2x/wk, at least 3 days apart, #8 tablets ____
- ☐ Child-Pugh B/C: 10 mg, PO 2x/wk, at least 3 days apart, #8 tablets ____

Prior authorization number (if known) _____

Prior authorization effective dates _____

Additional considerations: _____

Allergies: _____

Concurrent medications: _____

(Please note that Interconnect's limited specialty pharmacy network includes CVS Specialty, Accredo, and Walgreens.)

interconnectsupport

155. Analysts expressed concern over the FDA warnings, predicting that doctors would now hesitate to prescribe the drug based upon its updated safety profile. For example, Wells Fargo downgraded Intercept and reduced its price target from $265 to $95, noting that "the serious events in patients with mild or no baseline liver disease, treated with correct doses of OCALIVA, and the recommendation for increased monitoring could dramatically impact OCALIVA adoption in PBC." Jim Birchenough, *MD, ICPT: Downgrading To Market Perform*

on FDA Warning Letter for OCALIVA, Wells Fargo (Sept. 21, 2017). Morgan Stanley also lowered its price target from $75 to $50, explaining that, because the letter notes that some events occurred early in treatment, "some clinicians may find the immediate effects striking and potentially more indicative of causality, as well as having concerns about the longer-term, cumulative effect of the drug." Andrew Berens, *Ocaliva Regulatory, Commercial, and Clinical Uncertainties, Financing Overhang Keeps Us UW-Lowering PT to $50*, Morgan Stanley (Sept. 22, 2017); *see also* Jay Olson, *Moving to the Sidelines on Lack of Visibility, Down to Perform*, Oppenheimer (Sept. 22, 2017) (downgrading Intercept).

156. On February 1, 2018, the FDA announced that it had added a Black Box Warning to the label for Ocaliva that cautions physicians against overdosing higher-risk patients, recommends closer monitoring of patients while on Ocaliva, and requires that patients receive a Medication Guide that informs them about the potential for serious liver injury. *See* Press Release: FDA, *Ocaliva (obeticholic acid): Drug Safety Communication - Boxed Warning Added To Highlight Correct Dosing* (Feb. 1, 2018). A Black Box Warning is the FDA's most prominent label warning and is designed to call attention to serious or life-threatening risks. *See* FDA, A Guide to Drug Safety Terms at FDA, 2 (Nov. 2012).

ADDITIONAL SCIENTER ALLEGATIONS

A. *Respondeat Superior* And Agency Principles Apply

157. Intercept is liable for the acts of Intercept's and any subsidiary's officers, directors, employees, and agents under the doctrine of *respondeat superior* and common law principles of agency as all the wrongful acts complained of herein were carried out within the scope of their employment or agency with the authority or apparent authority to do so. The scienter of Intercept's officers, directors, employees, and agents is similarly imputed to Intercept under *respondeat superior* and agency principles.

B. Defendants Disregarded Available Information About Patients' Compliance With And Tolerance Of Ocaliva

158. Based upon the Briefing Package, Advisory Committee Meeting, and various approval memoranda provided to Defendants prior to the Class Period, Defendants were aware that the FDA believed it was imperative for patients with late stage PBC to receive a lower dose of Ocaliva (¶48) and that the FDA was concerned about the safety of Ocaliva, especially the potential of the drug to cause liver injury (¶49).

1. Defendants Disregarded Information About the Misdosing of Patients Using Ocaliva

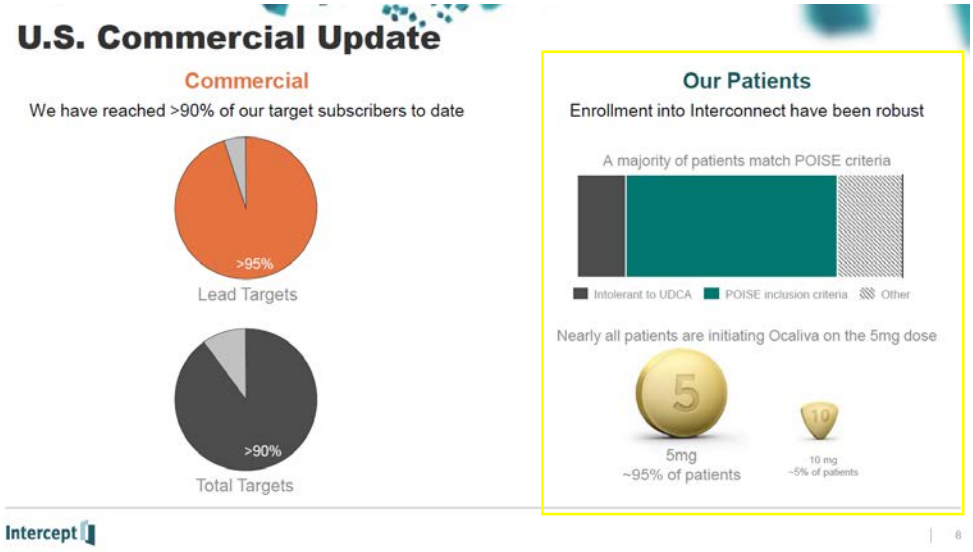
159. Defendants collected, had access to, and were in possession of material adverse facts showing that late stage PBC patients were not complying with the FDA-mandated weekly dosing regimen for Ocaliva. This is evident from the Company's compliance statements, the contemporaneous information the Company received during the Interconnect enrollment process, the contemporaneous information the Company received through its specialty pharmacies, and the serious adverse events reports the Company received and submitted to the FDA.

160. First, Defendants spoke about Ocaliva's dosing performance throughout the Class Period. As noted in ¶¶94-114, Defendants repeatedly assured the market that they were monitoring dosing (¶¶92-107), even noting that there were no specific dosing problems with late-stage PBC patients (¶98). To accurately speak about Ocaliva's dosing performance, Defendants would ***necessarily have had to review the dosing data*** they were referring to.

161. Second, through Interconnect's enrollment process, the Company collected in its internal system the prescription information for each patient along with the patient's ALP and bilirubin levels. ¶55. These data points gave the Company knowledge of which patients had late stage PBC and were therefore required to take the weekly dose of Ocaliva. Accordingly, at all

times during the Class Period, Defendants had access to the data on Intercept's internal system which would have indicated which patients had been misdosed. ¶58.

162. Defendants admitted pulling the information from the system. For example, on the second quarter earnings conference call on August 4, 2016, Kim stated that the Company's central database informed him that 15% of patients were not taking UDCA. Whether or not a patient was taking UDCA was listed on the Enrollment Form and then entered into the Company's central database. As well, on August 16, 2016, during the Wedbush PacGrow Healthcare Conference, Pruzanski stated that, presumably based upon the information received from the Enrollment Forms and compiled in the Company's internal system, the "patients largely match up well with our label and our Phase III population. We have seen an interesting mix of both combination with standard of care, urso. And then as shown here, 15% of patients, so far, intolerant to urso, . . . virtually all of the patients coming through have a confirmed diagnosis of PBC and are female again as expected." The 3Q 2016 Earnings Presentation powerpoint provided to investors on November 3, 2016 also provided metrics for the Ocaliva patient population that were pulled from the database (the relevant metrics have been highlighted by Lead Counsel with a yellow box for the Court's convenience):



163. Third, through Intercept's system of specialty pharmacies, Defendants had access to information indicating that late stage PBC patients were being prescribed the wrong dose of Ocaliva. As noted in ¶¶60, 61, Intercept maintained its own centralized system of three specialty pharmacies that processed and managed all prescriptions and refills and directly distributed Ocaliva to patients. This allowed Intercept to very closely track all Ocaliva prescriptions, and have a direct line of sight into the dosage taken by patients.

164. Fourth, the Company noted in adverse event reports that patients with late-stage PBC had received the incorrect daily dose of Ocaliva.

2. Defendants Disregarded Information About the Tolerance of Ocaliva

165. Defendants collected, had access to, and were in possession of adverse material facts related to Ocaliva's safety performance. This is evident from the Company's tolerance statements, the contemporaneous information the Company received through Interconnect, and the contemporaneous information the Company received through its federally-mandated pharmacovigilance duties.

166. First, Defendants spoke about Ocaliva's safety performance throughout the Class Period. As noted in ¶¶116-37, Defendants repeatedly assured the market that they were monitoring how patients were tolerating Ocaliva (¶¶117-30), even noting on several occasions that they had not observed any serious issues (¶¶118, 122, 132). To accurately speak about Ocaliva's safety performance, Defendants would ***necessarily have had to review the safety information collected by the Company***.

167. Second, as noted in ¶80, Defendants had access to information about Ocaliva's safety performance through its online patent services hub, Interconnect. Interconnect assigned Care Coordinators to patients who acted as points of contact to discuss any safety concerns or

other side effects that may have arisen through treatment. Thus, these Care Coordinators collected safety data from patients regarding their experiences on Ocaliva. ¶81.

168. Third, as noted in ¶77, Intercept collected information about the adverse events experienced by patients taking Ocaliva through the Company's standard pharmacovigilance duties. As part of its safety surveillance responsibilities, Intercept tracked the adverse event information it received from patients and healthcare providers and entered the information into an internal system that was designed to identify safety signals for the drug. ¶77. As Pruzanski boasted, Intercept maintained "***a very extensive safety database*** and when you're talking about chronic lifetime therapies like PBC chronic therapy certainly in NASH, ***safety first***." Mark Pruzanski, Presentation at RBC Capital Markets Health Care Conference (Feb. 23, 2017); *see also* Mark Pruzanski, Presentation at J.P. Morgan Health Care Conference (Jan. 11, 2017) ("[W]e have a very extensive safety database with over 675 patient years of exposure in our first indication alone.").

169. Along with entering this adverse event information into an internal system, to comply with its federally-mandated pharmacovigilance obligations, Intercept compiled detailed narratives of these adverse events. These narratives included information regarding the patient's medical history, dosage of the drug, the start and stop dates for the drug, concomitant medications, lab test results, outcomes attributed to the drug, and a description of the adverse event experience. ¶75. Interconnect facilitated this process as it made it easier for healthcare providers and patients to report adverse events to Intercept and for Intercept to then follow up with healthcare providers and patients to obtain additional information regarding the events. *See* ¶77. Accordingly, Defendants had access to information about how patients were tolerating

Ocaliva through the reports Intercept provided to the FDA and the information from those reports that was compiled into the Company's internal system.

C. Defendants Had A Duty To Monitor Patients' Tolerance Of Ocaliva

170. If Defendants did not access the information concerning patients' tolerance of Ocaliva, they recklessly disregarded FDA and regulatory imposed duties. First, as a condition of approval, the FDA instructed Intercept to monitor how patients tolerated Ocaliva by paying close attention to serious adverse events like liver injury. This is why the Decisional Memo noted, "[a]ll patients should be monitored for alterations in liver biochemical tests and development of liver-related adverse reactions." Amy Egan, MD, MPH, Office Deputy Director Decisional Memo, FDA, 19 (May 26, 2016). Thus, the FDA imposed a duty on Defendants to monitor adverse events and pay special attention to serious liver injury. Second, the Company's pharmacovigilance program, consistent with federal regulation, was designed to ensure that patients were tolerating the drug. ¶77. The Company therefore had a federally-mandated duty to collect accurate information about adverse events and monitor any potential safety signals that may arise. ¶¶74, 75.

D. The Importance Of Ocaliva To Intercept's Success

171. Because the fraud alleged herein relates to the primary business of Intercept, knowledge of the facts underlying the fraud may be imputed to the Individual Defendants. Indeed, Ocaliva was the Company's lead product and its only FDA approved product. Intercept admitted in its 2016 10-K that it is "dependent on the successful commercialization of Ocaliva® (obeticholic acid or OCA), for primary biliary cholangitis, or PBC. To the extent Ocaliva is not commercially successful, our business, financial condition and results of operations may be materially adversely affected and the price of our common stock. 2016 10-K at 33. Therefore, the Individual Defendants, as senior level executives, were in such positions at the Company to

access all material, non-public information concerning compliance and safety information concerning Ocaliva.

E. Intercept Has Intentionally Obstructed Lead Plaintiffs From Accessing Information From The European Medicines Agency

172. On March 23, 2018, Lead Counsel submitted an Application for Access to Documents, the European equivalent of a Freedom of Information Act request, to the European Medicines Agency ("EMA"). This request concerned Periodic Safety Update Reports ("PSURs") from December 12, 2016, the date the EMA approved Ocaliva, to June 11, 2017, the last available PSUR.

173. PSURs are reports, prepared by pharmaceutical companies, that provide an evaluation of the benefit-risk balance of a medicine. *See* European Medicines Agency, *Periodic Safety Update Reports*, http://www.ema.europa.eu/ema/index.jsp? curl=pages/regulation /document_listing/document_listing_000361.jsp&mid=WC0b01ac058066f910. PSURs summarize data on the benefits and risks of a medicine and include the results of all studies carried out with this medicine. *See Id.*

174. On May 15, 2018, the EMA granted Lead Counsel's Application. *See* Exhibit G attached hereto. The EMA wrote that these documents would be sent to Plaintiffs' counsel no sooner than 10 working days after consulting with Intercept. *Id.* However, by May 30, 2018, Intercept instituted a legal challenge that is still pending before the General Court of the European Union to prevent disclosure of the documents. *See* Case T-377/18: Intercept Pharma and Intercept Pharmaceuticals v. EMA.

F. Intercept Previously Paid $45 Million To Settle A Securities Fraud Action With Similar Claims

175. Concealing important safety information is Intercept's *modus operandi*. In 2016, Intercept paid a $55 million settlement, of which the Company paid $45 million out of pocket

(its insurance only covered $10 million), for securities fraud claims alleging that Intercept withheld significant safety information about a clinical trial involving Ocaliva. In that case, the court noted, when denying the Company's motion to dismiss in its entirety, that the Company chose "only to report the positive development" concerning the Phase IIb study and thereby engaged "in the sort of selective disclosure that creates a real possibility of misleading investors." *See In re Intercept Pharm., Inc. Sec. Litig.*, No. 14 CIV. 1123 NRB, 2015 WL 915271, at *7 (S.D.N.Y. Mar. 4, 2015). Pruzanski was a named Defendant in this case, and in any event confirms that Defendants were aware of their disclosure obligations to investors.

CLASS ACTION ALLEGATIONS

176. Lead Plaintiffs bring this action pursuant to Rule 23(a) and 23(b)(3) of the Federal Rules of Civil Procedure on behalf of themselves and a class consisting of all persons and entities who purchased or otherwise acquired Intercept common stock in the United States or on the NASDAQ Global Select Market between June 9, 2016 and September 20, 2017, inclusive, and who were damaged thereby (the "**Class**").

177. Excluded from the Class are Defendants, the officers and directors of Intercept at all relevant times, members of their immediate families and their legal representatives, heirs, agents, affiliates, successors or assigns, Defendants' liability insurance carriers, and any affiliates or subsidiaries thereof, and any entity in which Defendants or their immediate families have or had a controlling interest.

178. Also excluded from the Class are those who purchased or otherwise acquired Intercept common stock on foreign exchanges or purchased or otherwise acquired Intercept common stock outside of the United States, in accordance with the United States Supreme Court's decision in *Morrison v. Nat'l Australia Bank Ltd.*, 561 U.S. 247, 267 (2010) ("[I]t is in

our view only transactions in securities listed on domestic exchanges, and domestic transactions in other securities, to which § 10(b) applies.").

179. The members of the Class are so numerous that joinder of all members is impracticable. During the Class Period, Intercept common stock was actively traded on the NASDAQ Global Select Market exchange, which is an efficient market. While the exact number of Class members cannot be determined at this early stage, Lead Plaintiffs believe that thousands of people held Intercept common stock during the Class Period. Record owners and other members of the Class may be identified from records maintained by Intercept or its transfer agent and may be notified of the pendency of this action by mail, using a form of notice similar to that customarily used in securities class actions.

180. Lead Plaintiffs' claims are typical of the claims of the other members of the Class because Lead Plaintiffs and all members of the Class were similarly affected by Defendants' unlawful conduct as complained of herein.

181. Lead Plaintiffs will fairly and adequately protect the interests of the Class and have retained counsel competent and experienced in class action and securities litigation. Lead Plaintiffs have no interests that are contrary to or in conflict with those of the Class.

182. Common questions of law and fact exist as to all members of the Class, and predominate over any questions solely affecting individual members of the Class. The questions of law and fact common to the Class include, *inter alia*:

a) Whether the federal securities laws were violated by Defendants' acts as alleged herein;

b) Whether Defendants' publicly disseminated statements made during the Class Period contained untrue statements of material fact and/or omitted to state

material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading;

c) Whether and to what extent Defendants' material untrue statements and/or omissions of material fact caused the market price of Intercept's common stock to be artificially inflated during the Class Period;

d) Whether Defendants acted with the requisite level of scienter in omitting and/or misrepresenting material facts;

e) Whether the Individual Defendants were controlling persons of Intercept; and

f) Whether the Class members have sustained damages, and if so, the proper measure of damages.

183. Lead Plaintiffs know of no difficulty that will be encountered in the management of this action that would preclude its maintenance as a class action.

184. A class action is superior to all other available methods for the fair and efficient adjudication of this action because, among other things, joinder of all members of the Class is impracticable. In addition, since the damages suffered by individual members of the Class may be relatively small, the expense and burden of individual litigation would make it nearly impossible for members of the Class to bring individual actions.

LOSS CAUSATION

185. During the Class Period, as detailed herein, Defendants engaged in a scheme to deceive the market and a course of conduct that artificially inflated Intercept's stock price and operated as a fraud or deceit on Class Period purchasers of Intercept common stock by misrepresenting the Company's business and prospects. During the Class Period, Defendants misled investors regarding patients' compliance with the dosing regimen of Ocaliva and the

tolerability of Ocaliva. *See* ¶¶92-149. As a result of their purchases of Intercept common stock during the Class Period at artificially inflated prices, Lead Plaintiffs and other Class members suffered damages as the truth was revealed.

186. Defendants' wrongful conduct, as alleged herein, directly and proximately caused the damages suffered by Lead Plaintiffs and the Class.

187. Defendants' false and misleading statements and omissions in their SEC filings and other public statements during the Class Period directly and proximately caused damages to Lead Plaintiffs and the Class. On the strength of these false and misleading statements, the Company's stock price was artificially inflated to a Class Period high of $173.03 per share on July 29, 2016. Those misrepresentations and omissions that were not immediately followed by an upward movement in the Company's stock price served to maintain the share price at artificially inflated levels. The allegations herein suffice under both a corrective disclosure and a materialization of the risk theory of loss causation.

188. As relevant here, Intercept's stock first dropped after it published its "Dear Healthcare Provider" Letter before market open on September 12, 2017. This drop and its accompanying disclosure satisfies the corrective disclosure theory either alone or together with other disclosures because it revealed some aspect of the truth to the market regarding, *inter alia*, patients' compliance with the dosing regimen for Ocaliva and patients' tolerability of Ocaliva, and consequently removed a portion of the artificial inflation in Intercept's stock price and directly and proximately caused Lead Plaintiffs and the other Class members to suffer damages. ¶¶141, 142. The drop occurred on September 12, 2017, after Intercept issued its Dear Healthcare Provider Letter before the market opened. On this news, Intercept's common stock fell $22.73

per share from a close of $113.48 per share on September 11, 2017 to a close of $90.75 per share on September 13, 2017, a two-day drop of approximately 20%.

189. The second relevant drop occurred when the FDA issued its Safety Alert and Safety Announcement on September 21, 2017. This drop and its accompanying disclosure satisfies the corrective disclosure theory either alone or together with other statements because it revealed some aspect of the truth regarding, inter alia, patients' compliance with the dosing regimen for Ocaliva and patients' tolerability of Ocaliva, to the market and consequently removed a portion of the artificial inflation in Intercept's stock price and directly and proximately caused Lead Plaintiffs and the other Class members to suffer damages. ¶¶150-53. The drop occurred on September 21, 2017, when, in the middle of the trading day, the FDA issued its Safety Alert and Safety Announcement. On this news, Intercept's share price fell $36.53 per share, from a close of $98.12 per share on September 20, 2017 to close at $61.59 per share on September 22, 2017, a two-day decline of approximately 37.2%.

190. The aforementioned disclosures also suffice under the materialization of the risk theory of loss causation because Defendants' false and misleading statements and omissions in their SEC filings and other public statements during the Class Period (¶¶83-91) concealed the risks attendant to the fact that patients were receiving the incorrect dose of Ocaliva and that patients taking Ocaliva were experiencing Potential Side Effects (¶¶141-53).

CONTROL PERSON LIABILITY

191. The Individual Defendants, because of their positions with Intercept, possessed the power and authority to control the contents of Intercept's reports to the SEC, press releases, and presentations to securities analysts, money and portfolio managers, and institutional investors. Each of the Individual Defendants had a duty to (1) promptly disseminate complete, accurate, and truthful information about the improper dosing of late-stage PBC patients and the

occurrence of Potential Side Effects; (2) correct any previously issued statements that were materially misleading or untrue when made so that the market could accurately price the Company's securities based upon truthful, accurate, and complete information; and (3) update any previously-issued forward-looking statements that became materially misleading or untrue so that the market could accurately price the Company's securities based upon truthful, accurate, and complete information. Each of the Individual Defendants was provided with copies of the Company's reports and press releases alleged herein to be false or misleading prior to, or shortly after, their issuance and had the ability and opportunity to prevent their issuance or cause them to be corrected. Because of their positions and access to material non-public information available to them, each of the Individual Defendants knew that the adverse facts and omissions specified herein had not been disclosed to, and were being concealed from, the public, and that the positive representations and omissions which were being made were then materially false and/or misleading, and acted with culpable participation in the fraud.

THE FRAUD ON THE MARKET PRESUMPTION

192. At all relevant times, the market for Intercept's common stock was an efficient market for the following reasons, among others:

a) Intercept's common stock was listed and actively traded on the NASDAQ Global Select Market exchange (symbol ICPT), a highly efficient market;

b) As a registered and regulated issuer of securities, Intercept filed periodic reports with the SEC, in addition to the frequent voluntary dissemination of information;

c) Intercept regularly communicated with public investors through established market communication mechanisms, including through regular dissemination of press releases on the national circuits of major newswire services

and through other wide-ranging public disclosures such as communications with the financial press and other similar reporting services;

d) The market reacted to public information disseminated by Intercept;

e) Approximately 14 analysts followed Intercept's business and wrote reports which were publicly available and affected the public marketplace;

f) The material misrepresentation and omissions alleged herein would tend to induce a reasonable investor to overvalue Intercept's stock; and

g) Without knowledge of the misrepresented or omitted facts, Lead Plaintiffs and other members of the Class purchased Intercept common stock between the time that the Defendants made the material misrepresentations and omissions the time that the truth was revealed, during which time the price of Intercept common stock was artificially inflated by Defendants' misrepresentations and omissions.

193. As a result of the above, the market for Intercept securities promptly digested current information with respect to the Company from all publicly available sources and reflected such information in the securities' prices. The historical daily trading prices and volumes of Intercept securities are incorporated herein by reference. Under these circumstances, all those who purchased Intercept common stock during the Class Period suffered similar injuries through their purchases of common stock at prices which were artificially inflated by Defendants' misrepresentations and omissions. Thus, a presumption of reliance applies.

NO STATUTORY SAFE HARBOR

194. The safe harbor provisions for forward-looking statements under the Private Securities Litigation Reform Act of 1995 are applicable only under certain circumstances that do not apply to any of the materially false and misleading statements and omissions alleged in this Complaint.

195. First, the identified false and misleading statements and omissions herein are not forward-looking statements, but instead are statements of current or historic fact, or are actionable in context because they omit then-existing material facts.

196. Second, many, if not all, of the identified false and misleading statements herein were not identified as forward-looking statements.

197. Third, to the extent there were any forward-looking statements that were identified as such at the time made, there were no meaningfully cautionary statements identifying important factors that could cause actual results to differ materially from those in the purportedly forward-looking statements. Such statements were also not accompanied by cautionary language that was meaningful because any such warnings or "risk" factors contained in, or incorporated by reference in, the relevant press release, SEC filings, earnings class, or other public statement described herein were general, "boilerplate" statements of risk that would affect any pharmaceutical company, and misleadingly contained no factual disclosure of any of the specific details concerning the or similar important factors that would give investors adequate notice of such risks.

198. Fourth, to the extent there were any forward-looking statements, Defendants are liable for those false and misleading forward-looking statements because at the time each of those forward-looking statements was made, the particular speaker knew that the particular forward-looking statement was false, or, by reason of what the speaker failed to note, was materially false and/or misleading, and/or that each such statement was authorized and/or approved by a director and/or executive officer of Intercept who actually knew that each such statement was false or misleading when made.

CAUSES OF ACTION

COUNT I
Violations of Section 10(b) of the Exchange Act and Rule 10b-5 Against All Defendants

199. Lead Plaintiffs re-allege each allegation above as if fully set forth herein.

200. This Count is brought under Section 10(b) of the Exchange Act (15 U.S.C. § 78j(b)), and Rule 10b-5 promulgated thereunder by the SEC (17 C.F.R. § 240.10b-5), against all Defendants.

201. During the Class Period, Defendants violated Section 10(b) and Rule 10b-5 in that they: (a) employed devices, schemes, and artifices to defraud; (b) made untrue statements of material facts and/or failed to disclose material facts necessary in order to make the statements made, in light of the circumstances under which they were made, not misleading; and/or (c) engaged in acts, practices, and a course of business that operated as a fraud or deceit upon Lead Plaintiffs and others similarly situated in connection with their purchases of Intercept common stock during the Class Period.

202. Defendants, individually and in concert, directly and indirectly, by use of means or instrumentalities of interstate commerce and/or of the mails made the false and misleading statements specified herein, including the statements in SEC filings, presentations, press release, conference calls, and analyst reports regarding the safety of Ocaliva, whose truth they knowingly or recklessly disregarded when they failed to disclose material facts necessary to make the statements made, in light of the circumstances under which they were made, not false or misleading.

203. Defendants, individually and in concert, directly and indirectly, by use of means or instrumentalities of interstate commerce and/or of the mails, employed devices, schemes, and artifices to defraud and engaged and participated in a continuous course of conduct to conceal

the possible side effects and serious adverse events associated with the use of Ocaliva as well as the fact that patients were routinely being misdosed.

204. Defendants acted with scienter throughout the Class Period because each acted with either the intent to deceive, manipulate, or defraud, or with recklessness. Defendants possessed actual knowledge of the misrepresentations and omissions of material facts set forth herein, or acted with reckless disregard for the truth by failing to ascertain and to disclose such facts even though such facts were available to them, or deliberately refrained from taking steps necessary to discover whether the material facts were false or misleading.

205. Intercept is liable for the acts of the Individual Defendants and other Company agents and personnel referenced herein under the doctrine of *respondeat superior*, as those persons were acting as the officers, directors, and/or agents of Intercept in taking the actions alleged herein.

206. Lead Plaintiffs and Class Members purchased Intercept common stock, without knowing that Defendants had misstated or omitted material facts about the Company's operations and financial performance or prospects. In so doing, Lead Plaintiffs and Class members relied on false and misleading statements made by Defendants, and/or an absence of material adverse information that was known to Defendants or recklessly disregarded by them but not disclosed in Defendants' public statements.

207. Lead Plaintiffs and other Class members have suffered damages in that, in direct reliance on the integrity of the market, they paid artificially inflated prices for Intercept common stock, which inflation was removed from the prices of their shares when the true facts became known. Lead Plaintiffs and the Class would not have purchased Intercept common stock at the

prices they paid, or at all, if they had been aware that the market price had been artificially and falsely inflated by Defendants' materially false and misleading statements.

208. As a direct and proximate result of Defendants' wrongful conduct, Lead Plaintiffs and other Class members suffered damages in connection with their purchases or acquisitions of Intercept common stock during the Class Period after the truth was revealed.

COUNT II
Violations of Section 20(a) of the Exchange Act
Against the Individual Defendants

209. Lead Plaintiffs re-allege each allegation above as if fully set forth herein.

210. This Count is asserted against the Individual Defendants for violations of Section 20(a) of the Exchange Act, 15 U.S.C. § 78t(a), on behalf of all members of the Class.

211. During their tenures as officers and/or directors of Intercept, each of the Individual Defendants acted as controlling persons of Intercept within the meaning of Section 20(a) of the Exchange Act. By reason of their status as senior executive officers and/or directors of Intercept, the Individual Defendants had the power and authority to direct the management and activities of the Company and its employees, and to cause the Company to engage in the wrongful conduct complained of herein. Each of the Individual Defendants was able to and did control, directly and indirectly, the content of the public statements made by the Company during the Class Period, including the statements Lead Plaintiffs allege are false and misleading, thereby disseminating the false and misleading statements and omissions of fact alleged herein.

212. By virtue of their high-level positions at Intercept, and as more fully described above, each of the Individual Defendants had direct and supervisory involvement in the day-to-day operations of the Company. The Individual Defendants were able to and did influence and control Intercept's decision-making, including reviewing and controlling the content and dissemination of the documents that Lead Plaintiffs and the Class contend contained materially

false and misleading information and on which Lead Plaintiffs and the Class relied. The Individual Defendants were also in the position to prevent the issuance of these statements or to correct them prior to dissemination.

213. As set forth in Count I, Intercept committed a primary violation of Section 10(b) of the Exchange Act by knowingly and/or recklessly employing devices, artifices, and schemes to defraud, disseminating materially false and misleading statements and/or omissions, and/or engaging in acts, practices, or a course of conduct that operated as a fraud or deceit upon Lead Plaintiffs and the Class throughout the Class Period. By virtue of their positions as controlling persons of Intercept and as a result of their own aforementioned wrongful conduct, the Individual Defendants are liable pursuant to Section 20(a) of the Exchange Act, jointly and severally with, and to the same extent as the Company is liable under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder.

214. As a direct and proximate result of the Individual Defendants' wrongful conduct, Lead Plaintiffs and the Class suffered damages in connection with their purchases of Intercept common stock when the truth was revealed.

JURY TRIAL DEMAND

215. Lead Plaintiffs hereby demand a trial by jury on all triable claims.

PRAYER FOR RELIEF

WHEREFORE, Lead Plaintiffs demand judgment against Defendants as follows:

A. Determining that the instant action may be maintained as a class action under Rule 23 of the Federal Rules of Civil Procedure, and certifying Lead Plaintiffs as the Class representatives;

B. Requiring Defendants to pay damages sustained by Lead Plaintiffs and the Class by reason of the acts and statements alleged herein;

C. Awarding Lead Plaintiffs and the other members of the Class prejudgment and post-judgment interest, as well as their reasonable attorneys' fees, expert fees, and other costs; and

D. Awarding rescissory damages in favor of Lead Plaintiffs and the other Class members where appropriate against all Defendants, jointly and severally, for all injuries sustained as a result of Defendants' wrongdoing, in an amount to be determined at trial, including pre-judgment and post-judgment interest, as allowed by law;

E. Awarding such other and further relief as this Court may deem just and proper.

Dated: July 31, 2018

Respectfully submitted,

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